Evatuation of types and causes of dose administration errors

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Evaluation of Types & Causes of Dose Administration Errors

Submitted by

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Abstract

Medication incidents were reported by the National Patient Safety Agency in England and Wales as the third most common type of incidents in 2014. Incidents during the administration stage of the medication use process were reported as one of the most frequent types of medication incidents.

A retrospective, quantitative study using incidents reports was performed to determine the rate of medication administration incidents (MAI) relative to capacity and bed occupancy, types of incidents, drugs involved and severity of patient harm in medication incidents reported in one UK acute NHS hospital electronic reporting system over 12 months. The results confirmed that administration incidents were the most common incident stage, accounting for 49.6% (937/1889) of incidents in all stages of medication use processes. Most common incident types were drug omission and wrong dose, frequency, or infusion rate. The highest number of incidents was from Children's Services (215/937). However the number of medication administration incidents per 1000 bed-days was highest in the Perioperative, Critical Care and Pain directorate (16.9 MAIs/1000 patient days) followed by Children's Services (3.9 MAIs/1000 patient days), then Surgery (3.8 MAIs/1000 patient days). Morphine was the most common drug involved in MAI followed by enoxaparin. Weighting MAI rates by bed occupancy may be more appropriate measure than simple frequency of reported incidents from each clinical directorate and it is a better method of prioritising interventions for improvement. Determining the causes and contributing factors of MAIs is essential to plan intervention to reduce these incidents.

A semi-structure interview-based study was undertaken to investigate the views of nurses' and midwives about factors contributing to MAIs in hospitals. Twenty-five nurses with differing years of experience and from a range of clinical directorates were included in the study. Interviews were transcribed and thematically analysed using NVIVO software. Different factors related to the work environment, task, team, personal, organisational, and patients related factors were identified. Common work environment factors reported were staffing level, skill-mix, workload, night shifts, and frequent interruption / distraction during the preparation and administration of medicines. The main task factors included inappropriate checking and non-availability of laboratory results required for medication administration. Heparin, insulin, and drugs requiring dose adjustment based on blood tests were reported as high risk medications. Patient-specific factors identified were patients with complex clinical conditions, confused, unconscious or patients with dementia. Team factors such as poor communication within teams or with doctors were also considered risks. Organisational factors identified included inadequate training, lack of feedback on medication incidents, and unclear policies /guidelines. Finally, personal factors reported included nurses' fatigue and sleepiness particularly during long and night shifts, and inadequate knowledge, or skills about medicines.

The nurse interview study identified that fatigue / sleepiness were considered by nurses to significantly contribute to MAI particularly during long shifts and night shifts. Results from an American study which aimed to assess the impact of extended shifts and fatigue on medication safety supported a possible relationship between extended

work hours and the likelihood of error by nurses. However, this study relied on self-reported errors by nurses using logbooks. Therefore, the third study aimed to investigate whether nurses' fatigue and sleepiness during long shifts (12 hours shift) have an impact on the error rate and type during IV preparation and administration. This study was based on a direct observation method using simulated tasks of IV preparation and administration. Participants completed a baseline fatigue scale (OFER) scale for acute fatigue, chronic fatigue, and inter-shift recovery) at the start of their shift and their acute sleepiness was measured at different testing points: at start of shift, 8 hours and at end of the shift (12h) using Karolinska Sleepiness Scale (KSS). Both previously validated scales were short (8 to 15 questions). Nurses also prepared an injectable medication of similar level of complexity at the start and end of their shift. Nurses were presented with a prescription in the format routinely used on the study wards. The simulated task consisted of preparation of a medicine, including, as required: selection of materials, calculations, manipulations, labelling and set up for infusion. The simulated preparations were performed in ward medication preparation areas. Deviations from hospital standards for drug preparation, errors and preparation time were recorded. Using SPSS 22, the internal consistency of all subscales in the fatigue scale was assessed using Cronbach's alpha. The number and mean of deviations from standards and errors for each period of observation (pre and post shift) were calculated. Paired t-tests and Wilcoxon's signed-rank test were used to determine differences in fatigue levels, sleepiness scores, deviations from standards, means of errors and time needed between periods of observation (pre and post shift). 39 nurses were observed from medical wards (n=14), surgery wards (n=12), and intensive care units (n=13). Sleepiness scores were significantly higher at the end of shift compared to the beginning of the shift. The mean number of deviations from standards (6.33) at the end of the shift was significantly higher from the mean (4.18) at the beginning of the shift. However, the number of observed errors, and time needed did not significantly differ. McNemar's test showed a significant association between being sleepy and making errors at the end of the shift. However, this association was not significant at the beginning of the shift.

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Glossary of Terms

ADE:	Adverse drug event
ADR:	Adverse drug reaction
AHRQ:	Agency for Healthcare Research and Quality
AIMS:	Australian Incident Monitoring System
ANA:	American Nurses Association
APSF:	Australian Patient Safety Foundation
ASHP:	American Society of Health-System Pharmacists
BNF:	British National Formulary
CQC:	Care Quality Commission
DoH:	Department of Health
EPMA:	Electronic prescribing and medicines administration system
EU:	European Union
FDA:	Food and Drug Administration
GRIDA	Genetics, Rheumatology, Infection, Dermatology, and Allergy
IHI:	Institute for Healthcare Improvement
IoM:	Institute of Medicine
ISMP:	Institute for Safe Medication Practices
JADE:	Japan Adverse Drug Events
JCACO:	Joint Commission on the Accreditation of Healthcare Organizations

MAE:	Medication administration error
MAI:	Medication administration incident
ME:	Medication error
MHRA:	Medicines and Healthcare products Regulatory Agency
MI:	Medication incident
MUP:	Medication-use process
NCC MERP:	National Co-ordinating Council for Medication Error Reporting and Prevention
NHS:	National Health Service
NPSA:	National Patient Safety Agency
NRLS:	National Reporting and Learning System
OBD:	Occupied bed day
PSI:	Patient safety incident
UK:	United Kingdom
US:	United States
USP:	United State Pharmacopeia
WHO:	World Health Organization

Chapter 1. General introduction

1.1. Background

Patient safety is considered the foundation of good patient care. Although there is continuous development of healthcare services, healthcare itself can be a source of patient harm, especially with the inherent risk of medicines involved. Vincent (2011) stated that:

"As you will see however there is compelling evidence that, while healthcare brings enormous benefits to us all, errors are common and patients are frequently harmed. The nature and scale of this harm is hard to comprehend. It is made up, worldwide, of hundreds of thousands of individual tragedies every year in which patients are traumatised, suffer unnecessary pain, are left disabled or die. Many more people have their care interrupted or delayed by minor errors and problems; these incidents are not as serious for patients but are a massive and relentless drain on scarce healthcare resources." (Vincent 2011, p2)

A broad definition of patient safety is used by the World Health Organization (WHO):

"The prevention of errors and adverse effects to patients associated with health care." (World Health Organisation, p.1)

Vincent (2011) has also simply defined patient safety as:

'The avoidance, prevention and amelioration of adverse outcomes or injuries stemming from the process of healthcare' (Vincent 2011 p4).

The complexity of current healthcare systems provide considerable potential to harm patients, especially with new innovations and technology, which may bring unforeseen risks (Vincent et al. 2001). However, harm caused by medical treatment is now widely recognised and accepted by governments and healthcare organisations since much research and many reports have been published over the past 30 years on healthcare related harm in America, including the Harvard Medical Practice Study (Brennan et al. 2004) and the report of the US Institute of Medicine (IoM) (1999), Australia (Wilson et al. 1995), and UK (Department of Health 2000). Moreover, there is recognition that this

issue needs to be addressed at both a national and an international level (Legido-Quigley et al. 2008).

1.2. Patient safety and healthcare

The study by Schimmel (1964) was one of the first studies published on patient safety which prospectively investigated the occurence of hospital-induced complications in one teaching hospital. This analysis involving over 1000 patients, found that 20% (n=198) of admitted patients experienced at least one untoward episode (n= 240), of which 16 episodes were fatal. The "Harvard Medical Practice Study" (Brennan et al. 2004) is one of the pioneer studies in patient safety and is still influential today. In 1984 the study's authors found that adverse events (AEs) occurred in 3.7% of 30,121 reviewed patient records from 51 hospitals in New York. Furthermore, 27.6% of the identified AEs were preventable with 2.6% of these AEs leading to permanent injuries and 13.6% resulted in death. Another large Australian study reviewed more than 14,179 admissions to 28 hospitals in Australia and found that 16.6% (n= 2,302) of reviewed admissions were associated with an AE. Of the AEs, 51% were judged to be highly preventable (Wilson et al. 1995).

Despite the previous studies, medical errors were rarely discussed in the medical literature until the report of the US IoM 'To err is human' published in 1999 (Kohn et al. 2000). This report clearly set out the harm caused by medical errors in the US and also called for action and recommended strategies to improve patient safety (Kohn et al. 2000). In 2000, the UK Department of Health (DoH) published, "An organisation with a memory: learning from adverse events in the NHS" to set out the problem of failures in healthcare. The report revealed that AEs affected 10% of admissions causing nearly 400 deaths or serious injuries every year. The report also showed that around 28,000 complaints regarding clinical management were made a year in hospitals, costing the National Health Service (NHS) around £400 million/ year in claims. In one recent study, James (2013) estimated that preventable patient safety incidents (PSIs) were responsible for a minimum of 2 million serious injuries and 210,000 deaths occurring annually in the US. These figures were based on data from four large studies that used the Institute for Healthcare Improvement (IHI) Global Trigger Tool to detect PSIs from hospital medical records.

The World Health Organization (WHO) (2013) report of PSIs in hospitalised patients in the European Union (EU) revealed that between 8% - 12% of hospitalised patients were affected by PSIs and estimated that 50–70% of these incidents are preventable. Finally, in the UK, a recent report from the UK DoH and Secretary of State for Health (2013) stated that in 2011/2012, preventable PSIs harmed around half a million NHS patients (0.4%) and caused death to 3,000 (0.003%).

These studies revealed that AEs are common in healthcare and that they can be a serious source of patient harm. A large proportion of these events were considered preventable. Clinical governance had been introduced as a comprehensive strategy to address patient safety issues and improve the quality of healthcare on both individual and organisational levels (Scally and Donaldson 1998).

1.2.1. Clinical governance and patient safety

With the increasing complexity of clinical practice and the rapid development of medications, there is a need for systems which ensure safe provision of care for everyone (Kohn et al. 2000). Clinical governance is a system for NHS organisations and individuals which aims to improve the quality of healthcare delivered and ensure that a safe and high standard of care is provided and achieved. It consists of several key components which integrate together to form a high quality of healthcare (Figure 1.1) (Starey 2001). Clinical Governance was described by Scally and Donaldson (1998, p.62) as:

"A system through which NHS organisations are accountable for continuously improving the quality of their services and safeguarding high standards of care by creating an environment in which excellence in clinical care will flourish".

Figure 1.1. The elements of clinical governance (Starey 2001, p.2)

The DoH (1998) report, "The new NHS: modern, dependable" identified the essential actions required by organisations to ensure efficient clinical governance. These key actions involved: ensuring quality improvement procedures e.g., clinical audit are in place; assessing risk management and implementing risk reduction programs, applying evidence-based practice; implementing continuous development programs; developing leadership skills; and making responsibilities clear at clinical team levels. WHO and IoM have also recommended risk management and ensuring safety as major elements of effective and high quality healthcare (World Health Organisation 1989, Institute for Safe Medication Practices 2001). Therefore, clinical risk management was introduced into healthcare to reduce the occurrence and harm of preventable AEs and to minimise the harm results from AEs (Vincent and Moss 1995).

1.3. Medication safety incidents

1.3.1. Diversity of terms used for medication safety incidents

One of the main difficulties in studying medication safety is the multiplicity of terms and definitions used in describing medication related problems (Allan and Barker 1990, O'Shea 1999, Lisby et al. 2010, Kongkaew et al. 2013). For example, "medication incidents (MIs)", "medication errors (MEs)" "adverse drug event (ADEs)", "adverse drug reaction (ADRs)", and "potential adverse drug events" are all used to describe

problems with medication use (Australian Council For Safety And Quality In Health Care 2002). In a review of 160 patient safety websites, 25 different terms related to medication safety were found, with 119 different definitions (Yu et al. 2005). The term 'adverse event' was the most frequently defined term with 21 definitions, followed by 'error' (13 definitions). Another survey of ADEs in 132 intensive care units (ICUs) highlighted that sometimes different definitions were used within the same institution (Kane-Gill and Devlin 2006). The National Patient Safety Agency (NPSA) generated a standardised classification system for patient safety terms based on the incident type and the harm caused to patients (Table 1.1). The NPSA used the term "patient safety incidents" to cover all these terms.

Table 1.1. The National Patient Safety Agency patient safety incident taxonomy (from NPSA, 2004, p.97)

Old term	New term	Definition
Clinical risk	Patient safety	The identification, analysis and management of patient-related risks and incidents, in order to make patient care safer and minimise harm to patients
Adverse incident Adverse event Clinical incident Critical incident Medical error Clinical error Medical mistake Sentinel event	Patient safety incident	Any unintended or unexpected incident(s) that could have or did lead to harm for one or more persons receiving healthcare
No harm event	Patient safety incident (level of severity no harm)	A patient safety incident that caused no harm but was not prevented ('impact not prevented') or a patient safety incident that was prevented
Near miss/close call	Patient safety incident (prevented)	Any patient safety incident that had the potential to cause harm but was prevented, resulting in no harm to patients receiving healthcare

This lack of standard definitions is considered a main reason for underreporting of MEs (Caldwell et al. 2001, Armitage and Knapman 2003). Furthermore, it results in variable categorisation and hence rates of medication-related incidents between studies, making comparison between studies complicated (Ghaleb et al. 2010, Kongkaew et al. 2013) or

even invalid (Bates 1996). Additionally, building effective interventions to reduce ME occurrence and mitigating their impact requires reliable comparison of MEs, which cannot be achieved without an explicit, agreed-upon definition of ME and related terms (Aronson 2009, Ferner 2009). In this thesis, the term "medication incident" will be used, although when quoting verbatim the term used by the author (e.g. MEs) will be used.

1.3.2. Definition of medication errors

Different definitions of medication-related incidents were used by ME studies and institutions concerning medication safety. Some definitions of ME focused only on the part of the medication use process (MUP) after writing the prescription, and excluded errors in the prescribing phase. Bates (1996) argued that this definition of MEs was not accurate because prescribing errors are most likely to harm patients. Table 1.2 demonstrates examples of definitions that focus on the discrepancies between ordered and administered medicines/doses. Other definitions covered all stages of MUP. Table1.3 presents examples of definitions that included all MUP, using the term "error(s)" and related MEs to the preventability of errors. Ferner and Aronson (2006) proposed a conclusive and comprehensive definition of "medication error" as:

"A failure in the treatment process that leads to, or has the potential to lead to, harm to the patient"(Ferner and Aronson 2006 p1013).

The authors clarified the wider meaning of "treatment process" as the process that begins after the decision to initiate treatment and included prescribing, transcribing, compounding, dispensing, administration, and monitoring of therapy (Ferner and Aronson 2006). This definition was found to be the most robust when tested against different scenarios of MEs (Yu et al. 2005). The NPSA definition of MEs covered all medication process. The NPSA defined "medication incidents" as:

"Any incident where there has been an error in the process of prescribing, dispensing, preparing, administering, monitoring or providing medicines advice, regardless of whether any harm occurred or was possible" (National Patient Safety Agency 2009, p6).

Table 1.2. Definitions that covered all medication process, and used the term "error(s)"

Reference	Definition
Bates et al. (1995)	"Errors occurring at any stage in the process of ordering or delivering a medication, regardless of whether an injury occurred or the potential for injury were present. They include the entire range of severity, from trivial errors to life-threatening errors."
US Pharmacopeia (1995)	"Any preventable event that may cause or lead to inappropriate medication use or patient harm while the drug is in the control of the health care professional, patient or consumer"
American Society of Hospital Pharmacists (1998)	"Any preventable event that may cause, or lead to, inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer. (Such events may be related to professional practice, health care products, procedures, and systems, including prescribing, order communication, product labelling, packaging, compounding, dispensing, distribution, administration, education, monitoring, and use)."
Kohn et al. (2000)	"An error occurring at any stage in the process of delivering a medication. They include the entire range of severity, from trivial errors, such as orders that necessitated clarification or missing doses, to life-threatening errors, (such as a patient receiving a ten-fold overdose of a toxic agent."
NCC MERP (2005)	"Any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer. Such events may be related to professional practice, health care products, procedures, and systems, including prescribing; order communication; product labelling, packaging, and nomenclature; compounding; dispensing; distribution; administration; education; monitoring; and use"
Lisby et al. (2005)	"Errors in the medication process: ordering, transcription, dispensing, administration and discharge summaries"
Kopp et al. (2006)	An error occurring during the medication use process, regardless of whether an injury occurred or the potential for injury was present
National Patient Safety Agency (2007)	"Incidents in which there has been an error in the process of prescribing, dispensing, preparing, administering, monitoring, or providing medicine advice, regardless of whether any harm occurred or was possible"
Kongkaew et al. (2013)	"Any error in the prescribing, dispensing, or administration of a drug, irrespective of whether such errors lead to adverse consequences or not"
Wold Health Organization (2009)	"Any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer"
Lisby et al. (2012)	"An error in the stages of the medication process − ordering, dispensing, and administering and monitoring the effect − causing harm or implying a risk of harming the patient"
Australian Council For Safety And Quality In Health Care (2002)	"Failure in the (drug) treatment process that leads to or has the potential to lead to, harm to the patient and includes an act of omission or commission"
Ferner and Aronson (2006)	"Failure in the treatment process that leads to or has the potential to lead to harm to the patient."

Table 1.3. Examples of definitions focusing on discrepancies between ordered and administered medicines or doses

Reference	Definition
Allan and Barker (1990)	"Deviation from the physician's medication order as written on the patients chart."
Cooper (1995)	"A dose of medication that deviates from the physician's medication order on the patients chart."
Dean et al. (1995)	"A dose administered (or omitted) that deviated from the most recently written medication order for that patient"
Dean and Barber (2001)	"Any discrepancies between the medication prescribed and that administered"
Barker et al. (2002)	"A discrepancy between the dose ordered and the dose received"
Barker et al. (2002)	"Any discrepancy between the prescriber's interpretable medication order and what was administered to a patient"

1.3.3. The relationship between medication errors, adverse drug events, and potential adverse drug events

An overlap exists between medication-related incident categories. It is important to clarify the relationship between MEs, ADEs, and potential ADEs, when researching and seeking to improve safety in medication use (Bates et al. 1995, Morimoto et al. 2004). The term ADE involves injuries that result from medicines (Morimoto et al. 2004). Bates et al. (1995) defined ADEs as:

"Injuries resulting from medical interventions related to a drug" (Bates et al. 1995, p199).

In general, ADEs have been classified as "preventable ADE", which involves MEs resulting in patient harm, and "non-preventable ADE", which involve injury from medication not involving any error and in this case they are called ADRs (Von Laue et al. 2003). MEs that do not cause patient harm but have the potential to cause harm are "potential ADEs" (Morimoto et al. 2004). However, some MEs with little or no potential to cause patient harm are not considered potential ADEs, but are still considered MEs, e.g. when a non-critical medicine is administered late (Bates et al. 1995, Morimoto et al. 2004). Figure 1.2 represents the relationship between ADEs, MEs, and ADRs. The large circle represents the preventable drug events (all MEs, all potential ADEs, and preventable ADEs). The figure shows that only a small number of

MEs are potential ADEs or ADEs. Moreover, it shows that all potential ADEs are MEs and only a small portion of ADEs are originally MEs.

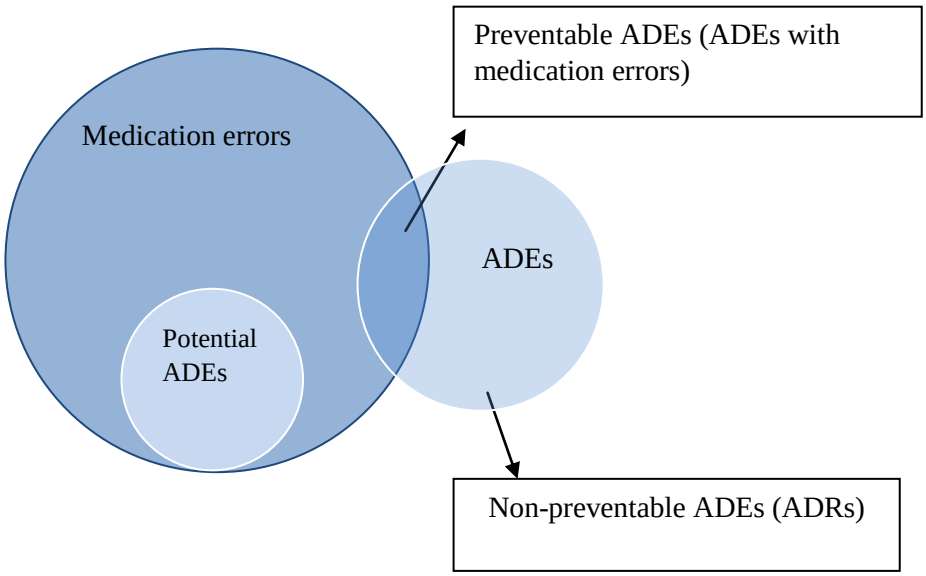

Figure 1.2. The relationship between medication errors, ADEs and potential ADEs (Bates et al. 1995, p.201)

1.3.4. Prevalence and preventability of medication related incidents in hospitals

The NPSA (2007) report revealed that around half a million prescriptions are written by doctors in hospitals every day. The cost of prescribed medicines in English hospitals accounted for 40% of the overall NHS expenditure in 2013-2014 compared to 37.5% in 2012-2013. From 2012 to 2014, medicine costs in hospitals rose by 15% to £5.8bn (Health and Social Care Information Centre (2014).

Medication related incidents are common and represent a large proportion of medical errors. Between 2005 and 2010, MIs were the second most common type of incidents reported to the National Reporting and Learning System (NRLS) in England and Wales, after patient accidents (Cousins et al. (2012). In this report, MIs accounted for 9.7% of all PSIs. The proportion of MIs increased from 8.2% to 11.2% between 2005 and 2010, to 11.4% (n=149,409) and 11.1% (n=158,951) in 2011 and 2012. In 2013 it was the third highest reported category, representing 11% of all reported incidents (n=175,406)

(National Patient Safety Agency 2013). A retrospective review of 1000 adult deaths in 10 acute hospitals in England in 2009 judged that 5.2% of the deaths had a 50% or greater chance of being preventable. 21.1% of these preventable deaths were due to inadequate drug or fluid management (Hogan et al. 2012). Another study of AEs in an NHS hospital used incident reports, active surveillance of prescription charts by pharmacists and record review at time of discharge and showed that ADEs comprised half of the total number of AEs detected and affected 10% of patients (Olsen et al. 2007).

In the US, about 10% of hospitalised patients suffered injuries caused by MIs. Furthermore, MIs appeared in 2-15% of hospital admissions and were also considered as a main cause of resulting injuries (Leape 1994). Another US study of 4,031 adult patients by Bates et al. (1995) identified 247 actual ADEs (11.5/ 1000 patient-day) and 194 potential ADEs (9.1/ 1000 patient-day). ADEs were judged preventable in 28% of all ADEs and in 42% (n=44) of the life-threatening and serious ADEs. Furthermore, in two large-scale studies of AEs in hospitalised patients, medication related AEs were found to represent 19% of all AEs in the Harvard Medical Practice Study (Leape et al. 1991) and the most common type of non-operative AEs in the Utah and Colorado study (Thomas et al. 2000).

Williams (2007) stated that MIs affect between 2 and 14% of patients admitted to hospitals. An analysis of 3,875 incident reports from three voluntary reporting systems in two US hospitals showed that MIs were the most common type of PSI, accounting for 29% (n=1094) of all reported incidents. Around 93% (n=1017) of these MIs were preventable. The proportion of preventable MIs represented 45.4% of all preventable incidents analysed in the study, which reflects the increased preventability of MIs compared to other types of incidents (Nuckols et al. 2007).

In Japan, 1,010 ADEs (17/ 1000 patient-day) and 514 MEs (8.71/000 patient-days) were identified in three tertiary care hospitals over six months. Of all ADEs, 14% were preventable and 1.6%, 4.9%, and 33% were fatal, life threatening, and serious, respectively (Morimoto et al. 2010). In Australia, the Quality in Australian Health Care Study (1995) reviewed the medical records of 14,179 admissions to 28 hospitals in Australia and revealed that 10.8% (n=249) of all AEs (n=2952) for inpatients were

medication related. Of these, 43% (n=108) were judged to have high preventability, 8% (n=20) resulted in death, and 17% (n=42) were associated with permanent disability (Wilson et al. 1995). In another Australian study, MIs represented 26% (n=7155/27000) of incidents reported in hospitals. (Runciman et al. 2003). A voluntary anonymous system in general practice in Australia, also showed that 50.1% (n=1294/2582) reports were medication related (Runciman et al. 2003) and that 2–4% of all hospital admissions (up to 30% in patients older than 75 years) were medication related with three quarters of these medication-related hospital admissions were preventable.

Von Laue et al. (2003) systematically reviewed the incidence and preventability of ADEs internationally in hospital settings and identified that ADEs affected between 0.7% and 6.5% of hospitalised patients and that up to 56.6% of these ADEs were determined to be preventable. ADEs were also found to be the cause of 2.4% to 4.1% of admissions with a preventability of up to 69% of these events.

1.3.5. Cost of medication incidents

In addition to the harm that may result from MIs, their costs and financial consequences may be significant. In the UK, the DoH (2004) reported that 10 to 20% of all AEs were medication related and estimated to cost the NHS £200-400 million with annual litigation costs estimated at £750 million (Smith 2004). The NPSA (2007) report estimated the cost of preventable harm resulting from medicines and revealed that preventable medication-related incidents cost the NHS a total of £774 million every year. This was the cost of preventable inpatient harms (£411m), avoidable admissions due to harm from medicines (£359m), and the cost of litigation (£4m).

Using a case-control method, Bates et al. (1997) estimated the cost of a total of 190 ADEs, of which 60 were preventable, for hospitalised patients in the US. They found that ADEs significantly increased the length of hospital stays for the ADE group by 2.2 days with an estimated post-event cost of $2595. In preventable ADEs, the length of hospitalisation increased by 4.6 days with estimated post-event cost of $4685. The IoM (2007) report estimated the extra cost of treating each preventable ADE that occurs in hospitals to be at $8,750 and with the assumption that 400,000 preventable ADEs occur every year, the total extra cost of all these medication-related events on the US healthcare system was estimated as $3.5 billion per year.

In Australia, Roughead and Semple (2009) suggested that around 190,000 hospital admissions occur every year due to medication-related problems, which account for 2-3% of admissions to Australian hospitals. This was estimated to cost $660 million. Approximately, 50% of these incidents were potentially preventable.

1.4. Medication use process

The term medication-use process refers to the multiple stages which are described in Figure 1.3 through which medications pass before reaching to the patient. In hospital settings, these stages encompass (1) prescribing e.g. by doctors or pharmacists; (2) transcribing; (3) preparing and dispensing; (4) preparing and administration, often by nurses; and (5) monitoring for both therapeutic effect and possible adverse events (Institute of Medicine et al. 2007). These stages form a complicated system that involves around 20 steps and consequently there are 20 opportunities for MEs to occur. Wrong medicine, wrong dose, wrong route, wrong time, and wrong patient are known as the classic types of medication errors and called the "five wrongs". These errors can occur at any stage of prescribing, transcribing, dispensing or administration. Moreover, adequate monitoring of therapeutic effect and adverse events is not always undertaken (Vogenberg and Benjamin 2011).

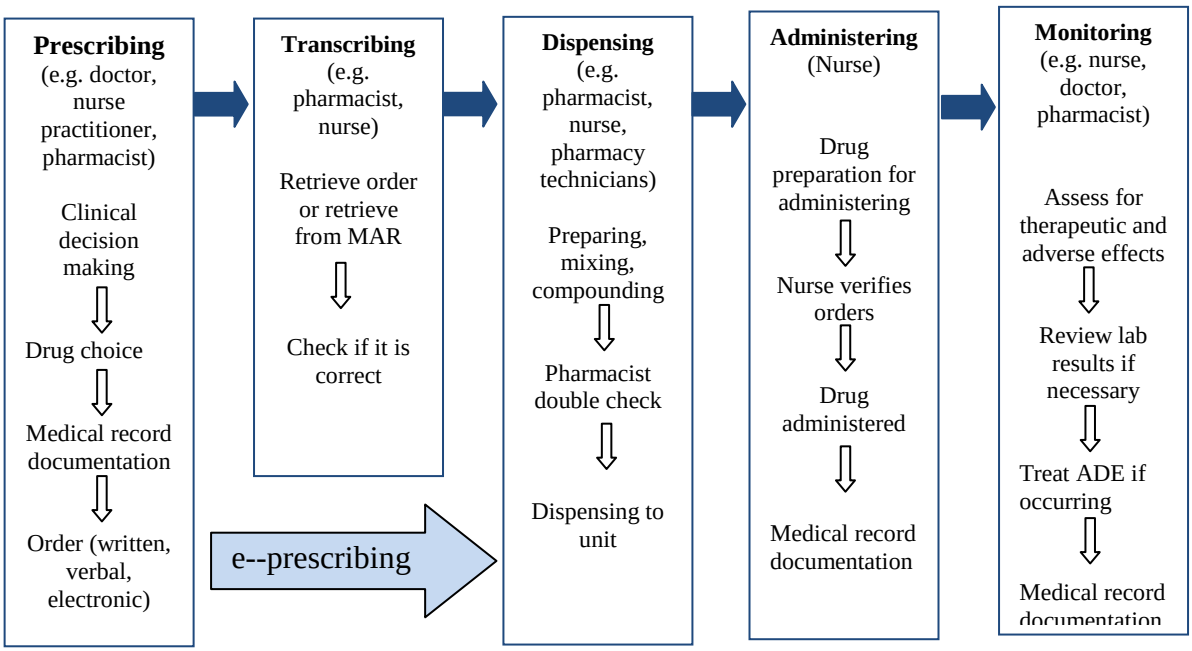

Figure 1.3. Medication-use process in hospitals (from IoM, 2007, p.68)

1.5. Medication incidents based on the stage of occurrence in the medication-use process

1.5.1. Prescribing and transcription Errors

Different definitions has been used by researchers to define prescribing errors (Tully 2012). However, the definition developed by Dean et al. (2000) is considered one of the most commonly used definitions in studies from the UK and Europe (Tully 2012). Dean and colleagues have defined prescribing errors as:

"A clinically meaningful prescribing error occurs when, as a result of a prescribing decision or prescription writing process, there is an unintentional significant (1) reduction in the probability of treatment being timely and effective or (2) increase in the risk of harm when compared with generally accepted practice." (Dean et al. 2000, p235)

Prescribing errors are common in hospitals and many MEs are caused by inappropriate prescribing, primarily made by junior doctors (Ashcroft et al. 2015). A UK prospective study conducted by Dean et al. (2002) assessed the incidence and clinical significance of prescribing errors in a UK hospital. The study involved 36,200 written medication orders over four weeks and identified a prescribing error in 1.5% (n=538) of the written orders. Most errors (61%, n=328) occurred during the order writing process, whereas 39% (n=210) of errors occurred during the prescribing decision process. The nature of errors involved dosing errors (54%, n=289), errors in deciding the need for medicine therapy (18%, n=96), giving instructions on how to supply the medicines (13%, n=69), and giving administration instructions (9%, n=51). Most of the serious errors (58%) occurred during the order writing process. The transcribing error rate was 1%. In total, 26% (n=142) of errors were potentially serious, of which, 58% occurred in the prescribing decision process.

Another recent UK study (Ashcroft et al. 2015) was conducted across 20 hospitals to compare the rate of prescribing errors made by junior doctors with those made by senior doctors and other prescribers. During the study period, pharmacists checked medication orders for prescribing errors. Of 124,260 checked medication orders 11,235 prescribing errors were identified in 10,986 orders giving a mean error rate of 8.8% for all prescribers. The results showed significantly higher rates of errors for doctors in

training compared to the rates for consultants. The error rates in prescriptions written by doctors in training was 8.6% for foundation year 1 doctors and 10.2% for foundation year 2 doctors, compared to 4.87% error rate for consultants. The most common type of errors identified in the study was the omitting of required medicine on admission (28.5 %), followed by under-dosage (10.9 %), and over-dosage prescribing (8.4 %).

In the US, researchers (Bates et al. 1995) assessed the incidence and preventability of ADEs in two US tertiary-care hospitals by reviewing self-reports and charts by nurses and pharmacists. They found that 49% (n=128) of 264 preventable ADEs occurred during the prescribing stage and that 11% (n=29) occurred during transcribing. In another US study to identify the nature of MIs (Winterstein et al. 2004), researchers analysed MIs reports in one tertiary hospital. The study found that 72.5% (n=174/240) of analysed MIs occurred in the prescribing stage and 6.3% (n=15/240) were in the transcribing stage.

In paediatrics, prescribing errors are also common. In the UK, the study conducted by Ghaleb et al. (2010) in five London NHS hospitals concluded that 13.2% (n=391/2955) of medication orders were associated with prescribing errors. Incomplete prescriptions (41.2%, n=161), use of abbreviations (24%, n=94), and dosing errors (11.3%, n=44) were the most common types of prescribing errors. A prospective cohort study for MEs in paediatric wards in two US teaching hospitals revealed that most of MEs occurred during the prescribing stage with 74% (n=454/616) errors reported, and 10% (n=62/414) occurring in the transcribing stage. The most common error type was dosing errors (34%) (Kaushal et al. 2001).

Lewis et al. (2009) conducted a systematic review of the prevalence, incidence and nature of errors associated with the prescribing stage in hospitals for adults or paediatric settings. The review which included 65 studies (22 from the UK and 25 from the US) identified 7% of medication orders associated with errors, which is equivalent to 52 errors/100 admissions and 24 errors/1000 patient days. It showed that the most common error was prescribing the incorrect dosage (Lewis et al. 2009).

The studies discussed above involved large numbers of patients and errors. These studies show that prescribing errors are common among adults and paediatric populations, although the rates of prescribing errors vary.

1.5.2. Dispensing error

Dispensing is considered core function of pharmacy professionals. The NPSA (2007) reported that around 900 million prescription items were dispensed every year by hospital and community pharmacies in England and Wales. In 2013, over 1.0 billion prescription items were dispensed in the community in England. Dispensing errors have been defined as:

"A discrepancy between a prescription and the medicine that the pharmacy delivers to the patient or distributes to the ward on the basis of this prescription, including the dispensing of a medicine with inferior pharmaceutical or informational quality."(Cheung et al. 2009, p.676).

Although dispensing errors can be associated with significant harm to patients, limited research has been performed to investigate the incidence and types of dispensing errors in hospital pharmacies. Errors during the dispensing stage were shown to have lower rates than during administration and prescribing stages (Bates et al. 1995, Ashcroft and Cooke 2006, Morimoto et al. 2010, National Patient Safety Agency 2013). In the UK, 11.1% (n=7,436) of MIs reported to the NPSA in 2009 from England and Wales hospitals occurred during the stage of preparation and dispensing of medicines compared to 53.4%, (n=34,137) during the administration stage and 17.5% (n=11,180) during prescribing (National Patient Safety Agency 2009). Another study (Beso et al. 2005) investigated dispensing errors identified in a NHS hospital pharmacy and found that 2.1% of 4,849 dispensed items had one or more dispensing errors.

In the US, an observational study for detected and undetected dispensing errors in a tertiary-care hospital identified 5,075 dispensing errors in 140,755 doses (3.6%). Of these errors, 79% were detected during routine checking, leaving 21% of observed errors undetected. Of undetected errors, 23.5% were potentially harmful, of which 0.8% were life threatening (Cina et al. 2006). In a French military hospital, Bohand et al. (2009) determined the error rate in 9,719 filled unit dose cassettes. The study found 706

dispensing errors (0.8%) in 88,609 filled unit doses involved in the study (including omitted doses). A study by Silva et al. (2011) investigated prescribing and dispensing errors associated with high-alert medications in a Brazilian paediatric unit and identified at least one dispensing error with each high-alert medication dispensed. A total of 1,707 dispensing errors were identified in 705 doses. In total, 723 (42.4%) of identified dispensing errors were also associated with prescribing errors.

James et al. (2009) conducted a literature review of international studies on the incidence and nature of dispensing errors. The review involved 18 studies from the UK and 18 studies from the US, which reported the errors from the hospital pharmacies. The review identified the rate of both prevented (i.e., errors intercepted before they leave the pharmacy) and unprevented dispensing errors (i.e., detected after the medicine has left to the units). In UK hospitals, the rate of prevented dispensing errors ranged from 0.11% to 2.7% (8 studies) and from 0.008 to 0.02% (n= 9 studies) for unprevented errors. Higher rates were found in US hospitals where prevented dispensing errors rates ranged from 0.06% to 18% (16 studies) while only one study reported the rate of unprevented dispensing errors at 0.75%. The most common types of unprevented errors were dispensing the wrong medicine, dosage, quantity, or strength. Labelling errors and dispensing the wrong medicine or strength were the most common types of prevented dispensing errors in both automated and manual systems. However, different studies from the UK revealed that automation systems significantly decreased medicine content errors (e.g., wrong medicine, wrong form, wrong quantity, and wrong strength) (Fitzpatrick et al. 2005, Franklin et al. 2008).

A large study undertaken by James et al. (2011) compared the rate and nature of prevented and unprevented dispensing incidents reported in five Welsh NHS hospital pharmacies. Amongst 221 670 items, the study found a significant differences between prevented incidents (n=131/100 000 items) and unprevented incidents (n=16/100 000 items). The study also found significant differences in the proportion of incidents involving wrong directions or warning on the label ($p = 0.02$), incorrect drug details on the label" ($p = 0.01$), dispensing incorrect strength ($p = 0.02$), and expiry date issues ($p = 0.002$) between prevented and unprevented incidents.

1.5.3. Medication administration errors

As medication administration is the last stage of MUP, the issue of errors during medication administration in hospitals has long been the focus of research. Medication administration was defined by the Nursing Interventions Classification as:

"Preparing, giving, and evaluating effectiveness of prescription and non-prescription medications" (Gonzales 2010, p555).

Medication administration incidents (MAIs) have been defined as:
"The administration of a dose of medication that deviates from the prescription, as written on the patient medication chart, or from standard hospital policy and procedures. This includes errors in the preparation, and administration of intravenous medicines on the ward" (Ghaleb et al. 2010, p114)

In the UK, the proportion of administration incidents was significantly higher than other stages of the MUP and varied between 46.5% (Ashcroft and Cooke 2006) and 83.3% (Maidment and Thorn 2005). Ashcroft and Cooke (2006) conducted a retrospective analysis of MIs reported over a 26-month period to an online reporting system in a large teaching hospital (1,000 beds). They found that 46.5% of the 495 submitted incidents were related to administration stage compared to 38.8% in the prescribing and 14.7% during the dispensing stage. A further retrospective study to analyse MIs reported to an online reporting system in acute and community hospitals and primary care facilities in Scotland over a 46-month-period also showed that administration incidents accounted for the majority of reported MIs (59%, n=1,571/2,666) (Alrwisan et al. 2011).

In US studies, the proportion of error during administration stage was slightly lower than prescribing (Bates et al. 1995, Leape et al. 1995, Kopp et al. 2006). Leape and his colleagues (1995) reviewed the patients' records in two hospitals and identified that 39% (n=130) of 334 errors occurred during the prescribing stage, and 38% (n=126) in the administration stage. Wrong dosage (27%, n=34), wrong administration technique (14%, n=18), administering the wrong medicine (12%, n=15), and omissions (8%, n=10) were the most common types of medication administration errors (MAEs). A retrospective study, conducted in a general hospital in Brazil to identify and classify

ADEs reported by nurses, revealed that 64.3% of 230 reported errors occurred during the medication preparation and administration stage (Silva et al. 2011).

Direct observation is a common method used to evaluate the rate, types, and severity of MAEs. Studies that used this approach identified the error rate to the total of opportunities of error (TOE). TOE is the sum of all doses ordered plus all the unordered doses given (Allan and Barker 1990). An international systematic review of 91 observational studies to review the prevalence and nature of MAEs found a median error rate of adults and/or paediatrics studies of 19.6%, including timing errors and 8.0% without timing errors. Timing errors (in studies reporting timing errors), omissions, wrong dosage, and unauthorised medicines were the most common errors in most studies (Keers et al. 2013). The median error rate in another systematic review of MAEs in hospitals was 10.5% (22.5% with timing errors) of TOEs in 34 cross-sectional studies. The median error rate in another 15 before and- after studies was 6.9% (22.5% with timing errors) of TOEs (Berdot et al. 2013).

Many observational studies have been conducted in the UK. The incidence of administration errors observed in the UK ranged from 3% to 10.7% (Dean et al. 1995, Kelly et al. 2011). Kelly et al. (2011) identified that out of 2,129 observed medicine administrations, 10.7% (n=228) involved errors. This increased to 38% when timing errors were included. Commonly observed errors were wrong time (72.1%, n=589), wrong preparation (8.0%, n=65), omissions (4.9%, n=40), wrong form (4.7%, n=38), and wrong dose (3.1%, n=25). A systematic review of UK observational MAE studies (n=16) identified an overall error rate of 5.6% (excluding timing errors) for non IV doses and 35% of IV doses. The review showed that MAEs in IV doses were five times more likely than non IV doses (McLeod et al. 2013).

In A US study of 36 healthcare facilities (24 hospitals & 12 nursing homes) accredited by Joint Commission on Accreditation of Healthcare Organizations, the rate of MAEs was 19% (n=605/3,216) of all administered doses as determined by a Barker et al. (2002). Although the rate was slightly lower at hospitals (16.4%, n=290/1,765) compared to nursing homes (21.7%, n=315/1,451), this difference was not significant (P=0.82). The most common types of errors were timing, omission, administering the wrong dose, and administering an unauthorized medicine. Poon et al. (2010) observed

6,732 medication administrations in medical, surgical, and ICU units in a 735-bed tertiary hospital in the US and found an 11.5% error rate (n=776) without timing errors. Wrong administration route (38.4%, n=289), wrong documentation (24.7%, n=192), and dosing errors (17.5%, n=163) were the most common errors. In total, 1.8% (n=123) of observed administrations were classified as potentially clinically significant, while 1.3% (n=88) were serious, and 0.03% (n=2) were life-threatening.

In an Australian study, Runciman et al. (2003) demonstrated that errors occur in 15–20% of dose administrations when ward floor stock systems were used and in 5–8% when unit dose supply systems were used. In a prospective Japanese study conducted to assess the incidence of ADEs, 68 errors (14.1%) were recorded at the administration stage compared to 319 errors (66.3%) at the prescribing stage, 8 errors (1.7%) during dispensing, and 83 (17.3%) monitoring errors (Morimoto et al. 2010). In Spain, Rodriguez-Gonzalez et al. (2012) identified that 22% (n=509/2,314) of administered doses in two medical units with automated prescribing and dispensing systems were associated with errors. Of these, 13.4% (n=68) were during the preparation stage and 86.6% (n=441) were at administration. The most commonly observed errors were "use of wrong administration techniques" (13.9%, n=321), mainly due to an interaction with food intake, wrong preparation i.e. wrong reconstitution/dilution (1.7%, n=40), omission (1.4%, n=32), and wrong infusion rate (1.2%, n=27). Of these, 95.7% did not cause harm, while 2.3% required monitoring, and 0.4% were associated with temporary harm (Rodriguez-Gonzalez et al. 2012). In France, an observational study was conducted by Tissot et al. (2003) in two units in a university hospital. The MAEs rates were 14.9% (with timing errors) and 11.1% (without wrong time errors) in all observed doses. The observed incidence of MAEs by a Malaysian observational study was 11.4% (n=127) of 1,118 observed doses (reduced to 8.7% if wrong timing errors were excluded). Of these, 10.4% were potentially life-threatening (Chua et al. 2009). Similar to the previous studies, incorrect administration time (25.2%, n=34), wrong administration technique (16.3%, n=22), and unauthorized medicine errors (14.1%, 19) were the most common errors. IV doses were found to be more likely to have errors compared with non IV routes (21.3% vs. 7.9%, $P < 0.001$).

In paediatrics, a systematic review of incidence of MEs in paediatric inpatients was conducted by Ghaleb et al. (2006) and involved eight observational studies from five

different countries including the UK. The study found that the observed MAE rate ranged from 0.6% and 10.3% when IV doses were excluded, and a higher rate of 18.2% and 27% was found of observed administrations when IV doses were included. Wrong administration route, wrong frequency of administration, and omission errors were the most common observed errors. More recent UK observational study also was conducted to identify MAEs in paediatric inpatients. The study involved 161 nurses preparing and administering medicines and identified 429 administration errors in 2,249 opportunities for error (19.1%) (Ghaleb et al. 2010). A study conducted in New Zealand showed that 44.6% (n=164) of errors occurred at the administration stage compared to 60.9% (n=224) during prescribing, 9.2% (n=34) at dispensing, and 14.9% (n=55) when monitoring (Kunac and Reith 2008).

In ICUs, medication related errors were particularly more common than other settings. This is because in ICU, patients receive about twice as many administrations as patients in general wards, and also most medicine administration involves calculations for bolus administration or continuous infusion (Kiekkas et al. 2011). Observational studies of MEs in ICUs identified that error rates ranged from 6.6% and 56.2% of observed administrations (Tissot et al. 1999, Van den Bemt et al. 2002). Valentin et al. (2009) conducted an international observational study of 113 ICUs from 27 countries including 16 units from the UK to evaluate MAEs with parenteral medicines. This multinational study showed that MAEs occurred in 7.3% (n=861\11,725) of administrations and affected 33.2% of patients. The study also showed that there were 74.5 errors per 100 patient days. Omissions (30.1%, n=386), wrong time (44.8%, n=259), and wrong dose (13.7%, n=118) were most common. In the US, Kopp et al. (2006) found that errors occurred in 26.7% of administrations in the ICU unit in a tertiary care hospital. Among errors with potential or actual harm (n=42), the most common types were omissions (48%, n=20), administering extra dose (14%, n=6), wrong administration technique (14%, n=6), and wrong dosage (12%, n=5). Details from studies using direct observation to detect MAEs are described in Table 1.4.

Higher error rates were observed in IV preparation and administration. The observed error rate in IV doses ranged from 7% (n=32/249) (Taxis and Barber 2003) to 31% (n=42/134) (Wirtz et al. 2003) during the IV preparation process. Whilst during the IV administration process, error rates ranged from 8% (n=118/1391) (Anselmi et al. 2007)

to 49% (n=53/109) (Wirtz et al. 2003). The overall rate of error in IV preparation and administration ranged from 25% (Bruce and Wong 2001) in one UK-based study to 69.7% in two studies from Australian and UK (Cousins et al. 2005, Westbrook et al. 2011). Taxis and Barber (2003) in an observational study in two UK hospitals identified that 49% of 430 observed IV doses were associated with one or more errors. The most common errors observed involved fast administration of bolus dose (37.9%, n=136/430), using wrong solvent or diluents (8%, n=36/430), preparing wrong dose (3%, n=12/430), and omissions (3%, n=12/430). In total, 1.2% of errors were potentially severe, 57.8% moderate, and 40.9% minor. Cousins et al. (2005) observed errors associated with preparation and administration of IVs in three European countries involving four hospitals in UK, one hospital in Germany and one hospital in France. The observed error rates were 69% (n=185/273) in UK sites, 52% (n=262/425) at the site in Germany, and 34% (n=34/100) at the site in France. Table 1.5 includes more details about some large scale observational studies of IV doses. Therefore, despite the development of patient safety research, MAEs in hospitals remain. Error rates during the preparation and administration of IV doses may be higher than non IV doses. Timing errors, omissions, and wrong dosage were the most common types.

A small number of the studies discussed above (Ho et al. 1997, Kopp et al. 2006) observed errors during both weekdays and weekends and covered all shifts (day, evening, and night) which made the results more reliable and representative. However, some studies observed administrations only on weekdays (Tissot et al. 1999, Van den Bemt et al. 2002, Tissot et al. 2003). Other researchers did not observe administration during evening or night shifts (Greengold et al. 2003, Tissot et al. 2003). Although the study of Ho et al. (1997) observed medication administration in one ward only, it has the advantage of comparing MAE rates between different periods i.e. weekdays vs. weekend, pharmacy open times vs. pharmacy closed times; first 48 hours after prescribing vs. remainder of course; first 48 hours after admission vs. remainder of stay. However, a number of studies did not clarify the observation times (morning, evening, or night) and whether the observations were performed during weekdays or weekends (Ridge et al. 1995). The reviewed studies also differed in the number of observation sites. Barker et al. (2002) used a large sample size (n=3,216 doses) from 36 institutions to identify the prevalence of medication errors. Such large samples may provide more representative findings (Barker et al. 2002).

Table 1.4. Large scale observational studies that reported on medication administration errors

Study/ country	Settings and sample size	Observed error rate	Common types of MAEs	Other findings
Ho et al. (1997) UK	**Settings: one** elderly care ward **Sample size:** 2,170 OEs and 119 MAEs	5.5% (119/2170) or 0.3 errors / patient day	Omissions (50.4%) Wrong dose (16%, 19) Wrong preparation technique (13%) Unauthorised dose (10.9%, 13).	• MAE rate was significantly higher on weekdays (6.4%) than weekends (4.0%). • MAE rate was higher during pharmacy opening hours (7.8%) than during the closing hours (4.6%).
Greengold et al. (2003) UK	**Settings:** 2 teaching hospitals. **Sample size:** 9,453 OEs and 1,457 errors.	General nurses: 14.9% (545) Medication nurses: 15.7% (912)	Wrong administration technique (6.4%) Wrong dose preparation (1.4%) Omissions (0.9%) Wrong dosage (0.8%) Wrong route (0.6%) Wrong Intravenous rate (0.2%)	
Chua et al. 2009 Malaysia	**Settings:** Haematology ward (22 beds) **Sample size:** 1118 doses with 127 analysed errors.	With timing errors 11.4% (127/1118) Without timing errors 8.7%	Incorrect time (25.2%), Incorrect administration (16.3%) Unauthorized medicine errors (14.1%).	• **Severity of MAEs:** Potentially life-threatening (10.4%), probably clinically insignificant (35.5%), minimal clinical significance (21.5%), definitely clinically significant (32.6%). • IV routes (21.3%) were more likely to be associated with MAEs than oral (7.9%).
Lisby et al. 2005 Denmark	**Settings:** One medical and one surgical ward **Sample size:** 2467 OEs in all stages and 1065 errors	Ordering (39%), transcribing (56%), dispensing (4%), administration (41%).	Lack of identity control (36,4%, 150), Wrong time (4.4%, 18) Wrong delivery (2.9%, 12) Wrong administration technique (1.9%, 8)	• **Severity of MAEs:** Fatal (1%, 2), serious (20%, 33), significant (32%, 53), non-significant (46%, 77).

Table 1.4. (Continued) Large scale observational studies that reported on medication administration errors

Study/ country	Settings and sample size	Observed error rate	Common types of MAEs	Other findings
Lisby et al. 2005 Denmark	**Settings:** One medical and one surgical ward **Sample size:** 2467 OEs in all stages and 1065 errors	Ordering (39%, 167), transcribing (56%, 310), dispensing (4%, 17), administration (41%, 166).	Lack of identity control (36,4%, 150), Wrong time (4.4%, 18) Wrong delivery (2.9%, 12) Wrong administration technique (1.9%, 8)	• **Severity of MAEs:** Fatal (1%, 2), serious (20%, 33), significant (32%, 53), non-significant (46%, 77).
Ghaleb et al. (2010) UK	**Settings**: (10 paediatric wards) **Sample size:** 161 nurses and 2294 doses were observed.	19.1% (429/2294)	Wrong preparation (20.7%, 89) Wrong administration rate of IV(19.8%, 85) Wrong time (18.7%, 80) Left medicine by patient's bedside without checking administration (10.0%, 43) Incorrect dose (9.3%, 40) Wrong administration technique (5.4%, 23) Omissions (5.1%, 22).	• **Severity was not reported.**
Franklin et al. (2007) UK	**Settings:** one surgical ward **Sample size**: 1644 OEs (pre) 1178 OEs (post)	Pre: 8.6% (141/1644) Post: 4.4% (53/1178)	• **Pre**: Omissions (4.1%, 68), fast administration of IV bolus (1.9%, 31), and wrong dose (1.8%, 29) • **Post**: Omissions (4.1%, 68), fast administration of IV bolus (0.4%, 5), and wrong dose (0.4%, 5).	

Table 1.4. (Continued) Large scale observational studies that reported on medication administration errors

Study/ country	Settings and sample size	Observed error rate	Common types of errors	Other findings
(Dean et al. 1995) UK and US	**Settings:** 2 UK and US university hospitals **Sample size**: UK: 2756 OEs, US: 919 OEs	UK 3% US 6.9%	**UK:** Omission (58%, 49) Wrong dose (14%, 12) Wrong formulation (10%, 8) Wrong medicine (7%, 6) **USA:** Omission (22%, 14) Wrong dose (30%, 19) Unordered medicine (25%, 16)	
Rodriguez-Gonzalez et al. (2012) Spain	**Settings:** two clinical units in a tertiary teaching hospital **Sample size:** 2314 administrations for 73 patients were observed	Total error rate: 22% (509/2314) 13.4% (68) in preparation and 86.6% (441) in administration.	Use of wrong administration techniques (13.9%, 321) Wrong reconstitution/dilution (1.7%, 40) Omission (1.4%, 32) Wrong infusion rate (1.2%, 27) Wrong dose (0.8%, 19).	• **Severity:** No damage (95.7%), no damage but monitoring required (2.3%), and temporary damage (0.4%).
Barker et al. 2002 US	**Settings:** 18 hospitals (36 sites; up to 4 units per site) **Sample size:** OEs= 3216	With timing errors 18.8% (605/3216) Without timing errors 10.8%	Timing errors (43%) Omission (30%) Wrong dose administration (17%) Unauthorized medicine (4%)	• 7% of errors were judge as potential ADEs. • **The significant potential risk factors:** Morning and evening shift, and IV administration. .
Valentin et al. (2009) Multinational*	**Settings**: 113 ICUs from 27 countries (17 from the UK) **Sample size:** 1,328 patients and 11,725 administrations.	• 861 MAEs affected 441 patients (33.2% of all patients observed). • 74.5 events/100 patient days.	**No, error/100 patient days:** Wrong time (386) Missed medication (259) Wrong dose (118), Wrong medicine (61)	• **Impact of errors:** 12 patients (0.9% of the study population) experienced permanent harm or died

* Prospective cross-sectional study using multi-entry questionnaire

Some studies were conducted in a limited number of units or wards, and therefore results were not extrapolated to other settings (Ho et al. 1997, Taxis and Barber 2004, Chua et al. 2009). Furthermore, studies conducted in limited sites provided a small sample size such as the study by Chua et al. (2009) when only one haematology ward of a teaching hospital (22 beds) in Malasya was studied and only 127 errors were analysed. Additionally, the study of Tissot et al. (2003) in one university hospital observed only 523 opportunities for error and only 78 MAEs were detected.

In some observational studies, the observers compared the information collected from the observation with the original prescription to detect errors (Barker et al. 2002). However, other studies applied wider definitions of MAEs when also detected the variations from safe medication practices (Greengold et al. 2003, Chua et al. 2009) or recommendations of the manufacturers and the protocols of each unit (Tissot et al. 2003). Furthermore, Van den Bemt et al. (2002) detected any deviation from written, printed, or verbal medication orders, the drug information sheets provided by the manufacturer, from the information in a handbook on injectable drugs, or from general nursing procedures used in the hospitals.

1.5.4. Monitoring errors

Medication monitoring is considered the last stage of the MUP. The aim of monitoring is to ensure the efficacy and safety of medication administered. Monitoring errors were defined as:

"A monitoring error occurs when a prescribed medicine is not monitored in the way which would be considered acceptable in routine general practice." (Alldred et al. 2008, p318).

Although studies have shown that inappropriate monitoring of patients can result in harm to patients, monitoring incidents, which are also known as 'ameliorable incidents' are not always included in the research of medication safety compared to other stages of MUP, particularly those occurring in hospitals (Bates et al. 1995, Lisby et al. 2005, Kopp et al. 2006).

Table 1.5. Large scale observational studies that reported preparation and administration errors of IV doses

Reference/ Country/	Study settings	Observation data	Error rate	Details of errors types	Severity
Taxis and Barber (2004) Germany	1 surgical ward and 1 surgical ICU.	22 nurses were observed. 34% of all prescribed doses were observed	**Overall rate** (48%, 58/122) **Preparation errors** (19%, 23/122) **Administration errors** (23%, 28/122) **Both types of errors in** (6%, 7/122).	***Preparation errors:*** Errors in solvent/ diluents (20%, 24/122), wrong dose (2%, 3/122), Omission (1%, 1/122), unauthorised medicine (2%, 2/122) ***Administration errors:*** Fast bolus dose (2%, 3/122), incompatibilities (25%, 31/122).	Potentially minor errors (13%, n=16), potentially moderate (31%, n=38), potentially severe errors (3%, n=4)
Taxis and Barber (2003) UK	One teaching hospital and one non-teaching general hospital (10 wards)	Data were collected on 6-10 consecutive days on each ward including weekends and covered all times of drug rounds.	**Error rate** (49%, 212/430) **Preparation errors** (7%, 32/430) **Administration errors** (36%, 155/430) **Both types of errors** (6%, 25/430).	Errors in multiple step preparations (14%, 50/345), ready for administration (0%), bolus dose injection (73%, 172/235), intermittent infusion (9%, 15/163) **Errors details:** ***Preparation errors:*** errors in solvent/diluents (8%, 36/430), wrong dose (3%, 12/430), and omission (3%, 12/430). ***Administration errors:*** fast bolus dose (peripheral line) (30%, 127/430), fast bolus dose (central line) (8%, 36/430), incompatibilities (3%, 12/430).	Potentially severe errors (1%, n=3), potentially moderate errors (29%, n=126), And potentially minor errors (19%, n=83)
(Wirtz et al. 2003) UK & Germany	3 large teaching hospitals	Total of 615 observed doses**:** (337 preparations and 278 Administratio ns	**(TBP):** **Preparation errors:** 22%, **administration errors**: 27% **(TGP):** **Preparation errors:** 23%, **administration errors** 49% (**GSP):** **Preparation errors:** 31% , a**dministration errors** 22%	***Common preparation errors*** **TBP:** wrong dose 3%, wrong dosage form 7%, omissions 10%, and wrong prep. tech. 3% **TGP:** wrong dose 21%, omissions 1%, and wrong preparation tech. 1% **GSP:** wrong dose 5%, wrong dosage form 2%, omissions 20%, wrong preparation tech. 1% ***Common administration errors*** **TBP:** wrong rate 27%. **TGP:** wrong rate 37%, and compatibility errors 17% **GSP:** wrong rate 20%, and compatibility errors 2%	• Potential minor outcome 27% • Moderate to severe clinical outcome 74%

TBP = traditional British pharmacy service; TGP = traditional German pharmacy service; GSP = German satellite pharmacy service

Table 1.5. (Continued) Large scale observational studies that reported preparation and administration errors of IV doses

Reference/ Country/	Study settings	Observation data	Error rate	Details of errors types	Severity
Cousins et al. (2005) UK Germany, and France	**UK:** medical and surgical wards in 4 hospitals **Germany:** 2 surgical ICUs and 1 general surgical ward **France:** One Immunology department	Total of 824 preparations and 798 administrations were observed.	**Preparation and administration error rates excluding labelling errors and omissions:** UK (69%, 185/273) Germany (52%, 262/425) France (34%, 34/100)	**UK:** labelling error (43%), wrong diluents (1%), wrong rout (1%), wrong rate (48%), wrong time (18%), wrong dose or infusion volume (0.5%) . **Germany:** labelling error (99%), wrong diluents (49%), wrong rate (21%), wrong time (2%), wrong dose or infusion volume (2%). **France:** labelling error (20%), wrong diluents (18%), wrong rate (5%), wrong time (4%), wrong dose or infusion volume (5%)	Not observed
Westbrook et al. (2011) Australia	6 wards in 2 teaching hospitals	107 nurses and 568 doses were observed in both sites	**Error rate** 69.7% (396 of 568 IV doses were associated with at least one error with total of 511 errors)	***Procedural failures*** *(Deviation from the procedure):*73.9% of doses have at least one procedural failure. ***Clinical errors:*** wrong rate (73.3%), wrong volume (33.3%), wrong mix (5.8%), drug incompatibility (0.8%). ***Medicines associated with more errors:*** antiulcerant (93%), antiemetic (75%), anti-infective (67%), steroid (67%), narcotic (67%), diuretic (50%).	• 25.5% of errors were rated as serious errors (23% of bolus doses and 10% of infusion doses caused serious errors
Anselmi et al. (2007) Brazil	Three hospitals.	Total of 2709 observations	**Preparation errors** (8.5% , 118 /1391) **Administration errors** (5%, 66/ 1315) **Total rate:** 6.7% (184/2709)	**Preparation errors: Hospital 1:** omission (5.8%), wrong dose (90.9%). **Hospital 2:** omission (11%), wrong dose (2%). **Hospital 3:** wrong dose (7.4%), omission (2.9%). **Administration errors: Hospital 1:** wrong dose (1.3%), omission (0.8%), wrong patient(0.1%). **Hospital 2:** wrong dose (2.2%), omission (1.1%), wrong patient (1.1%). **Hospital 3:** wrong dose (5.7%), omission (3.4%).	Not provided

The NPSA report (2007) showed that 3.8% (n=2424) of reported MIs in the hospitals were monitoring incidents. A study in six general medical practices found that less than a third of patients prescribed diuretic medicines had their blood electrolyte levels monitored (Clayton et al. 2006). In another study, less than half of 1,200 epileptic patients were adequately monitored for their anticonvulsive levels (Thapar et al. 2001). In the UK, Barber et al. (2009) evaluated MIs in 55 care homes and found 14.7% (n=32) of administered medicines that needed monitoring were associated with monitoring errors. In the US, Kuo et al. (2013) found that 14% (n=85/605) of inpatient MIs were related to monitoring. In a Japanese study, Morimoto et al. (2010) revealed that 17% (n=83) of preventable and potential errors occurred at the monitoring stage**.**

1.6. Analysis of incidents causation

Since the mid-1980s, several research studies have investigated the human and organizational factors affecting safety in healthcare. At the beginning, the focus was mainly around the work of anaesthetists and ICUs (Reason 1995). Later, the interest in the human factors spread wider in different health care settings and several medical specialties (Vincent et al. 1993, Vincent et al. 1998, Taylor-Adams and Vincent 2004, Vincent 2004, Cornish and Jones 2012). Furthermore, the collaboration between medical specialists and experts in human factors yielded more acceptances of accident causation models, which were developed for other domains such as nuclear power and were applied in healthcare settings. Reason's model for organisational accidents, which was developed to help analysis of error causation and in developing error prevention methods in complex industrial systems, has been adapted for healthcare settings (Reason 1995).

Analyses of accidents causation in medicine, and before in other fields such as aviation and nuclear power, have focused on the background of these accidents i.e. pre-existing factors related to the system which results in the conditions in which errors occur rather than the individuals who make errors (Reason 1990, Vincent et al. 1998). In MEs, the vast majority were found to be multifaceted and resulting from system failures in which clinicians work (Cohen and Shastay 2008). This concept that errors mainly result from the systems failure, not from individual negligence, became fundamental in new strategies to address safety in healthcare (Leape et al. 2002).

1.6.1. Human contribution theory

Reason's organisational accidents model was developed mainly to detect the chain of actions that lead to an accident. This considered the individuals' actions, and then, most importantly, the background conditions in which individuals were working and investigate the organisational context where the accident occurred (Reason 1990). For a better understanding of human contribution in accidents, Reason's model classified the human failure in two ways: active failures (or person approach) and latent failures (or system approach). This classification distinguishes failures which have immediate outcomes (active failures) from those which may take long time for their negative outcome to appear (latent failure). Each model has its model of causation and philosophies of error management (Reason 1990).

Active failures are those unsafe actions committed by individuals' in the front line i.e. in medicine, those who are in direct contact with patients, e.g., physicians, pharmacists, and nurses and therefore, their adverse outcomes are immediate. Active failures involve "errors" and "violations". Based on the definition of error; "failure of planned actions to achieve their desired goal" (Reason 1995, p.81); Reason further classified errors into two categories based on the psychological way the failure occur: unintended and intended actions (Figure 1.4). Unintended actions occur when the plan itself is good but the failure was in the execution or action and involves slips and lapses. Slips relate to observable actions and are usually associated with attentional or skills based failures i.e. the person intended to do something but did something else by mistake, e.g. picking up the wrong syringe or medicine while lapses are related to memory based failure (Reason 1995).

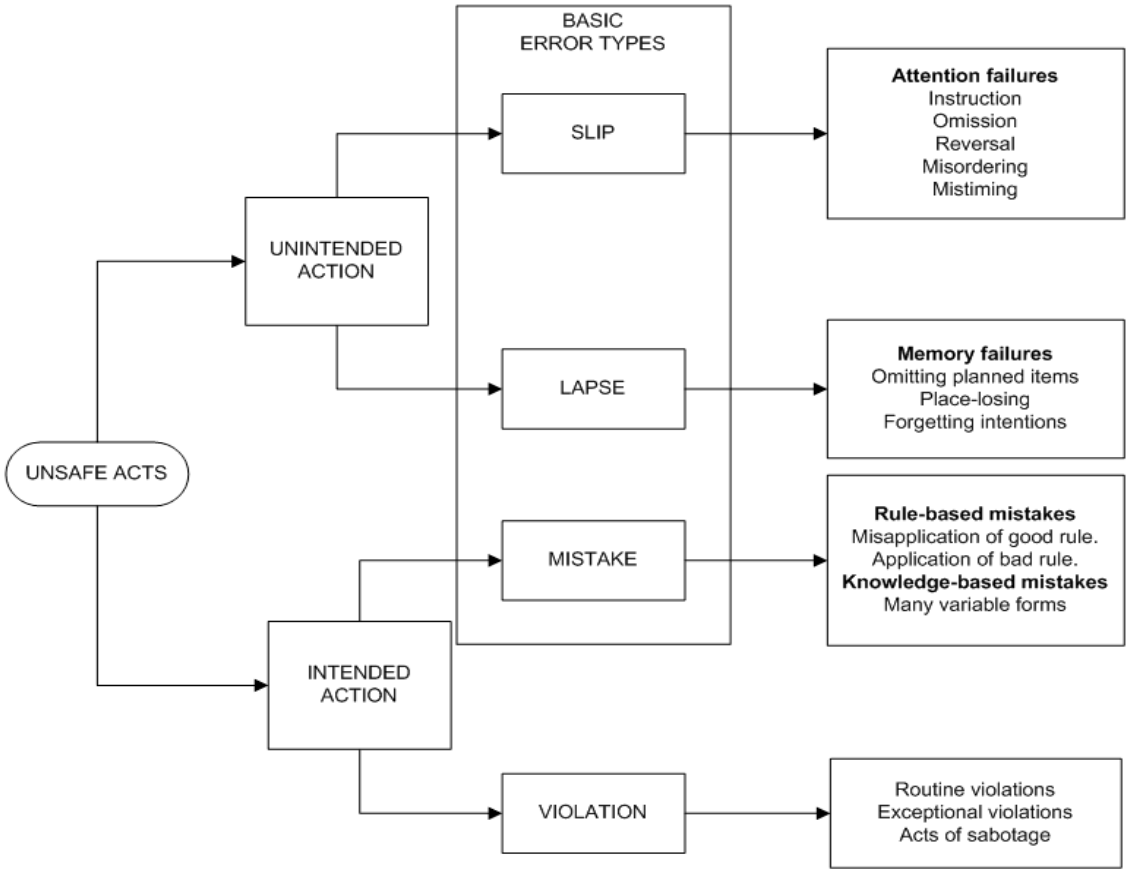

Figure 1.4. Reason's psychological classification of human errors (Reason 1990, p.207)

Conversely, intended actions can be divided into mistakes and violations. Mistakes, also called 'failures of intention', involve good execution of an incorrect plan i.e. the actions may go as intended, but the plan itself or its bath is inappropriate to achieve the desired outcome. Mistakes can be rule based mistakes, where the error comes in different forms: misapplication of a good rule, or application of a bad rule i.e. error in judgement or knowledge based mistakes i.e. errors due to lack of knowledge. Therefore, in all error types (slips and lapses, and mistakes), there is a deviation. In slips and lapses, the deviation occurs at the level of action or execution, while with mistakes, the action may go as intended but the plan itself deviates from the appropriate pathway to achieve its objectives. In mistakes, the usually failure comes from higher levels in the organisation where planning and designing intentions are made.

In contrast, violations involve any deliberated deviations from safe practices, procedures, standards, or rules i.e. the actions were intended. In comparison with errors, which mainly result from informational problems (e.g. forgetting, inattention, lack of knowledge etc.), violations are more linked to motivational problems such as low morale, inadequate supervision, and lack of concern. Another difference between errors and violations is that errors can be treated by improving the quality and delivering the necessary information within the organization, while violations usually need motivational and organizational solutions (Reason 1995).

Latent failures, the second perspective in Reason's causation model, are usually those adverse outcomes resulting from decisions at higher organisational levels i.e. committed by people who are not directly involved in the workplace. They are seen as the origin of errors and can exist for a long time without any apparent adverse outcomes until they combine with local triggers when their consequences are disclosed (Reason 1995). In medicine, latent failures are mainly the liability of people in management and of senior clinicians who are responsible for taking decisions within the institution (Reason 1995, Vincent et al. 1998). These failures have consequences in workplace conditions in which errors occur e.g. heavy workload, distractions, and inadequate staffing. Thus, the two main differences between active and latent failures are firstly, the length of time that the adverse outcome requires to occur, and secondly, where the failure occurs in the organisation (Reason 1990).

1.6.2. The 'Swiss cheese' model of system accidents

In the systems approach, barriers, and safeguards are designed to act as defensive layers to protect the organisation, as well as the potential victim from local hazards. Although these defences could be effective, Reason's Swiss cheese model (Reason 1990) explained these defences as like slices of Swiss cheese and both active failure and latent failures (through errors and violations producing conditions) can act as holes in the system defences for the error to pass and cause an adverse event (Figure 1.5).

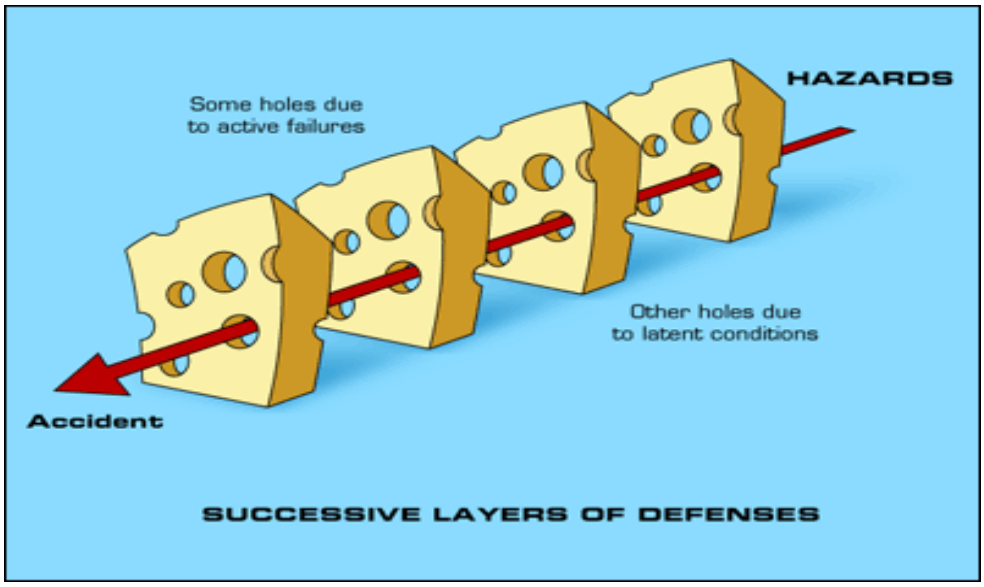

Figure 1.5. Reason's Swiss cheese error causation model (Reason 2000, p.393)

1.6.3. Analysing and investigating clinical incidents

Based on Reason's model of organisational accidents, Vincent et al. (1998) developed a model (Figure 1.6) to provide better explanation and understanding of the anatomy and aetiology of organisational accidents and facilitate analysis of adverse incidents in medical organisations. As shown in Figure 1.6, the sequence of the accident begins when the latent failures (management or organisational factors) are created by organisational and management negative decisions. The latent failures then transmit through different organisational pathways until they reach the work place (e.g. the operating theatre, or wards) where the local climate of errors and violation conditions are created in the work-place e.g. understaffing, increased workload, poor supervision. To define the conditions of work and associated latent failures which promote the unsafe acts, Vincent et al. (1998) developed a framework to integrate the whole hierarchy of background conditions and factors that may contribute to the risk and unsafe practice for use as a tool to systematically analyse and monitor the safety performance of medical organisations. The framework involved the main features encountered in medicine such as factors related to work environment, organisation and management, individuals (staff), teams, tasks, and patient characteristics (Vincent et al. 1998).

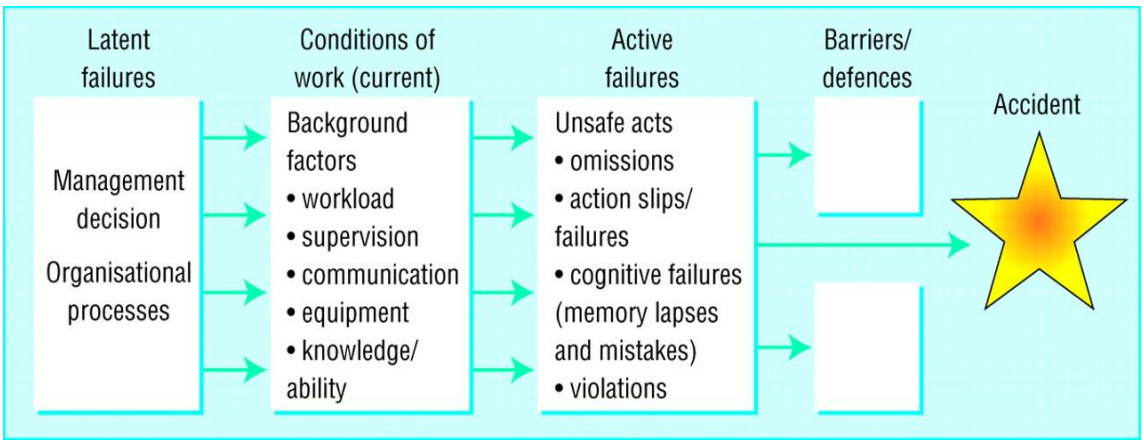

Figure 1.6. Vincent's organisational accident model for clinical incidents (Vincent et al. 1998, p.1155)

1.6.4. Medication incident detection methods

Many MIs are undetected and many detected incidents are not reported (Smith 2004) (Figure 1.7). Detecting MIs is the initial step of reporting incidents and then using information in incident reports to avoid further recurrence and build a safe healthcare system. Alerts and reports about MIs are very important to increase the awareness of the risks of these incidents and to encourage healthcare organisations to improve their performance (Vincent et al. 2006). Different national healthcare systems and regulatory agencies such as the Food and Drug Administration (FDA), United States Pharmacopeia (USP), Joint Commission on the Accreditation of Healthcare Organizations (JCAHO), European Medicines Agency (EMEA), Australian Patient Safety Foundation (APSF), Medicines and Healthcare Products Regulatory Agency (MHRA), and NPSA release these alerts and reports (Montesi and Lechi 2009).

Different methods have been used to measure and study MIs and ADEs in healthcare settings. The reliability and validity of methods used is important not only to study MIs and ADE but also to measure the efficacy of applied strategies and interventions to reduce the rate of errors. The most commonly used techniques are observational methods, chart review, and incident reports, along with critical incident techniques, attending medical rounds, interviewing healthcare providers, and comparing medication administration records with physicians' orders (Allan and Barker 1990, Flynn et al. 2002, Thomas and Petersen 2003, Tully and Franklin 2015). Another less frequently used method includes urinalysis to check the presence and absence of medicines, and

detecting omission errors using doses returned in the medication chart (Allan and Barker 1990, Barker et al. 2002).

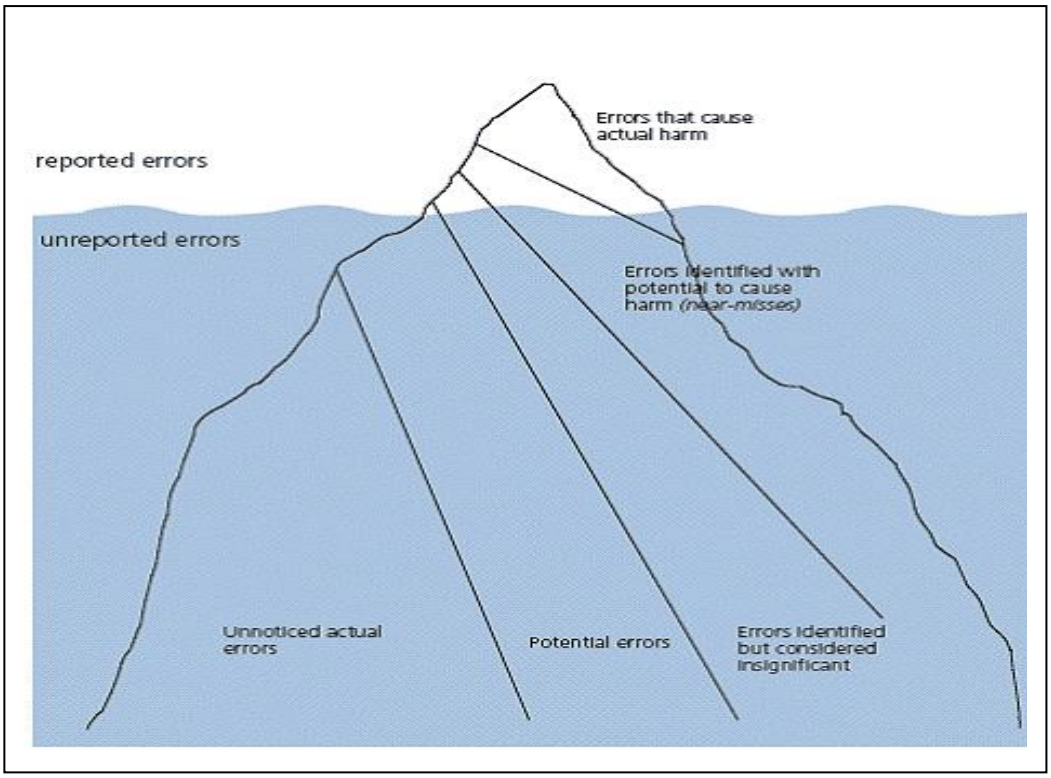

Figure 1.7. The medication error iceberg (from Smith, 2004, p.22)

Direct observation, chart review, and incident reports have been found to be the most common methods used for checking administration incidents (Allan and Barker 1990). Thomas and Petersen (2003) summarised the most common methods used to detect MEs and AEs and reviewed the advantages and disadvantages of each method (Table 1.6).

1.6.4.1. Direct observation

Observation was found to be the most accurate method of detecting MIs, particularly administration incidents. The efficacy and reliability of observational methods in detecting MIs over other methods such as incident reporting and chart review has been demonstrated (Allan and Barker 1990, Barker et al. 2002). Flynn et al. (2002) compared three methods of detecting MIs in 36 US healthcare facilities. Among 2,556 doses, direct observation detected 300 MIs (11.7%), while record review detected 17 (0.7%), and incident report analysis detected only 1 (0.04%). However, the average cost of error detection with observation ($4.82) was much higher than the chart review ($0.63).

One of the strengths of observational methods is the additional information and comments collected by the observer, which could be useful in identifying causes and contributing factors related to errors (Barker et al. 2002). Moreover, the objectivity of observational method overcomes problems associated with reporting incidents, such as the willingness of the reporter to report, and remembering to report during high workload, which are considered to be the main causes of underreporting incidents (Allan and Barker 1990, Barker et al. 2002).

The most concerning limitation of the observational method is the impact of the observer on the subject. However, to avoid the influence of the observation on the activity of the observed person, Alan and Barker (1990) suggested using the disguised observation technique developed by Barker and McConnell in 1962. Dean and Barber (2001) assessed the reliability of direct observation in studying MAEs and examined the potential effect of observation on MAE rate by comparing the percentage of omissions documentation between observation and non-observation periods. The study found no difference in the percentage of documented omissions between the observation and non-observation periods. This study concluded that observing nurses during medication administration at a UK hospital did not significantly affect the rate of MAE.

Another limitation that can occur in observational studies is that the data collected were limited to the observed days and shifts, and even during the observation shift, whereby observation usually did not cover all administered doses. As in most studies, more than one member of staff is administering medicines at the same time; however, there would usually be only one or two observers. Therefore, some administrations may have been unobserved. In addition, in such research only specific wards or units were studied and hence may not be representative of all wards and hospitals. In general, the direct observation method was found to be more reliable and objective, but also more expensive when compared with chart review and incident reports (Allan and Barker 1990, Barker et al. 2002).

Table 1.6. Advantages and disadvantages of methods used to measure errors and adverse events in health care (from Thomas and Petersen (2003, p.62))

Error measurement method	Advantages	Disadvantages
Morbidity and mortality conferences and autopsy	• Can suggest latent errors • Familiar to health care providers and required by accrediting groups	• Hindsight bias • Reporting bias • Focused on diagnostic errors • Infrequently and non-randomly utilized
Malpractice claims analysis	• Provides multiple perspectives (patients, providers, lawyers) • Can detect latent errors	• Hindsight bias • Reporting bias • Non-standardised source of data
Error reporting systems	• Can detect latent errors • Provide multiple perspectives over time • Can be a part of routine operations	• Hindsight bias • Reporting bias
Administrative data analysis	• Utilizes readily available data • Inexpensive	• May rely upon incomplete and inaccurate data • The data are divorced from clinical context
Chart review	• Utilizes readily available data • Commonly used	• Judgements about adverse events not reliable • Expensive • Medical records are incomplete • Hindsight bias
Electronic medical record	• Inexpensive after initial investment • Monitors in real time • Integrates multiple data sources	• Susceptible to programming and/or data entry errors • Expensive to implement • Not good for detecting latent errors
Observation of patient care	• Potentially accurate and precise • Provides data otherwise unavailable • Detects more active errors than other methods	• Expensive • Difficult to train reliable observers • Potential Hawthorne effect • Potential concerns about confidentiality • Possible to be overwhelmed with information • Not good for detecting latent errors
Clinical surveillance	• Potentially accurate and precise for adverse events	• Expensive • Not good for detecting latent errors

1.6.4.2. Chart review

Chart review is a retrospective method based on practice sources, such as medical charts, prescription data, and administrative records. The chart review method was found to be less accurate than direct observation in measuring the error rate (Flynn et al. 2002, Montesi and Lechi 2009). However, it is useful in detecting prescribing errors. Chart review also has another limitation, which the incomplete documentation in the medical chart. Some incidents and ADEs may not be noted on charts and may thus be missed (Thomas and Petersen 2003). Bates et al. (1993) raised an additional issue regarding the reliability of data in chart review method when they acknowledged in their study that notes in some critical areas such as ICUs may be more detailed than on general wards resulting in detection bias. Most studies that have employed chart review have also used additional data collection methods. These additional methods included solicited reports from nurses and pharmacists, voluntary reports (Bates et al. 1993), reviews of medication sheets by a trained reviewer (Bates 1995a), and laboratories and incident reports (Morimoto et al. 2010).

1.6.4.3. Incident reports

Although the incident report method has the advantage of providing data from all hospital departments over a long period of time, compared with the observational method which provides data in a selected time period and from specific units, many studies discussed the limitations of underreporting. This makes this method inadequate for error detection (Allan and Barker 1990, Flynn et al. 2002, Thomas and Petersen 2003). Flynn and colleagues (2002) have concluded that incidents reports are less accurate and effective than direct observation and chart review in detecting administration incidents. In a UK study, Olsen et al. (2007) compared three different methods to detect AEs on the same group of patients. Out of 288 patients' discharges, a real-time record review found 67 MIs, pharmacy surveillance (proactive surveillance of inpatient prescriptions and medication administration) detected 30 MIs, and incident reporting detected 11 MIs (Olsen et al. 2007). In this study, only three MIs were detected by both record review and pharmacist surveillance, and only one MI was detected by both record review and incident reporting. The results of this comparison suggest that using more than one method to detect MIs, increase the validity of the results as each method detects different incidents.

1.7. Harm classification of medication safety incidents

Patient safety incidents are usually classified according to their actual or potential clinical significance (harm) caused to patients. However, determination of the clinical impact of incidents is subjective, depending on the experience and knowledge of the reporter. Therefore when patient safety incidents are reported to the NRLS, the system does not require grading the potential harm or recurrence but only require actual patient harm according to the NPSA categorisation of level of harm (Table 1.7) (National Patient Safety Agency 2004).

Table 1.7. NPSA terms and definitions for grading the severity of patient harm (NPSA, 2007, p 54).

Harm	Definition
No harm	"Impact prevented: any patient safety incident that had the potential to cause harm but was prevented, resulting in no harm to the person(s) receiving NHS-funded care." "Impact not prevented: any patient safety incident that ran to completion but no harm occurred to the person(s) receiving NHS-funded care."
Low	"Any patient safety incident that required extra observation or minor treatment, and caused minimal harm to the person(s) receiving NHS-funded care."
Moderate	"Any patient safety incident that resulted in a moderate increase in treatment, and which caused significant but not permanent harm to the person(s) receiving NHS-funded care."
Severe	"Any patient safety incident that resulted in permanent harm to the person(s) receiving NHS-funded care."
Death	"Any patient safety incident that directly resulted in the death of the person(s) receiving NHS-funded care."

The NPSA developed a risk matrix to be used as guidance for consequence scoring of PSIs (National Patient Safety Agency 2008). Based on the clinical consequence caused by the incident and the likelihood of recurring, incidents are scored from 1 to 25 where the higher scores mean higher incident risk (Figure 1.8).

Many other scales have been developed and used for severity classification of medication safety incidents. Dean and Barber (1999) developed a validated scale to assess the severity (potential harm) of MIs using a linear rating scale from zero (no

patient effect) to 10 (death). This scale does not require the researcher or reporter to know the patients' outcomes and is based on potential outcomes. This scale is not affected by the healthcare profession of the judges. The National Co-ordinating Council for Medication Error Reporting and Prevention (NCC MERP) (2001) developed an index of nine categories to grade the severity of MIs to ensure the consistency of MI reporting (Figure 1.9).

1.8. Classifications of medication safety incidents

Several methods of classification have been used to classify medication related incidents. In addition to the classification according to the stage of the MUP in which they occur, MIs classification can be contextual (according to the time, place, stage, or person involved), modal (the way in which the incident occurred such as omission, wrong dose, or medicine), or psychological classification, which focused on the psychological mechanism of the events rather than describing them (classification of incidents according to whether they are knowledge-, or rule-based, slips, or lapses, etc.) (Ferner and Aronson 2006). The psychological classification of Ferner and Aronson (2006) is based on Reason's (1990) human error theory. It was suggested that such classification provides a better understanding of incidents, which help in suggesting strategies to avoid error. Table 1.8 includes examples for strategies for reducing incidents of different psychological classes of MEs. Morimoto et al. (2004) used numerous criteria to classify MIs, ADEs, potential ADEs, and MEs. They classified them according to stage (prescribing, transcribing, dispensing, administration, or monitoring), preventability (preventable or non-preventable ADEs), severity (section 1.7), person responsible (e.g., nurse, pharmacist), and ameliorability (ameliorable or non-ameliorable ADE) (Figure 1.10). ADEs are classified as "ameliorable ADE", when the severity or duration of injury can be reduced if an action is taken, and "non-ameliorable ADE" when the severity or duration of injury cannot be controlled (Morimoto et al. 2004).

Likelihood score	**1 (Rare)**	**2 (Unlikely)**	**3 (Possible)**	**4 (Likely)**	**5 (Almost certain)**
Frequency How often might it/does it happen	This will probably never happen/recur	Do not expect it to happen/recur but it is possible it may do so	Might happen or recur occasionally	Will probably happen/recur but it is not a persisting issue	Will undoubtedly happen/recur, possibly frequently
Frequency (time-framed)	Not expected to occur for years	Expected to occur at least annually	Expected to occur at least monthly	Expected to occur at least weekly	Expected to occur at least daily
Probability	<0.1%	0.1 – 1%	1 – 10%	10 – 50%	>50%

Domains	**1 (Negligible)**	**2 (Minor)**	**3 (Moderate)**	**4 (Major)**	**5 (Catastrophic)**
Impact on the safety of patients, staff or public (physical/psychological harm)	Minimal injury requiring no/minimal intervention or treatment. No time off work	Minor injury or illness, requiring minor intervention Requiring time off work for >3 days Increase in length of hospital stay by 1-3 days	Moderate injury requiring professional intervention Requiring time off work for 4-14 days Increase in length of hospital stay by 4-15 days RIDDOR/agency reportable incident An event which impacts on a small number of patients	Major injury leading to long-term incapacity/disability Requiring time off work for >14 days Increase in length of hospital stay by >15 days Mismanagement of patient care with long-term effects	Incident leading to death Multiple permanent injuries or irreversible health effects An event which impacts on a large number of patients

Likelihood score	**1 (Rare)**	**2 (Unlikely)**	**3 (Possible)**	**4 (Likely)**	**5 (Almost certain)**
5 Catastrophic	5	10	15	20	25
4 Major	4	8	12	16	20
3 Moderate	3	6	9	12	15
2 Minor	2	4	6	8	10
1 Negligible	1	2	3	4	5

1–3 Low risk **4–6 Moderate risk** **8–12 High risk** **15–25 Extreme risk**

Figure 1.8. The National Patient Safety Agency matrix for classifying the risk of associated with patient safety incidents (from NPSA, 2008. p 6-10

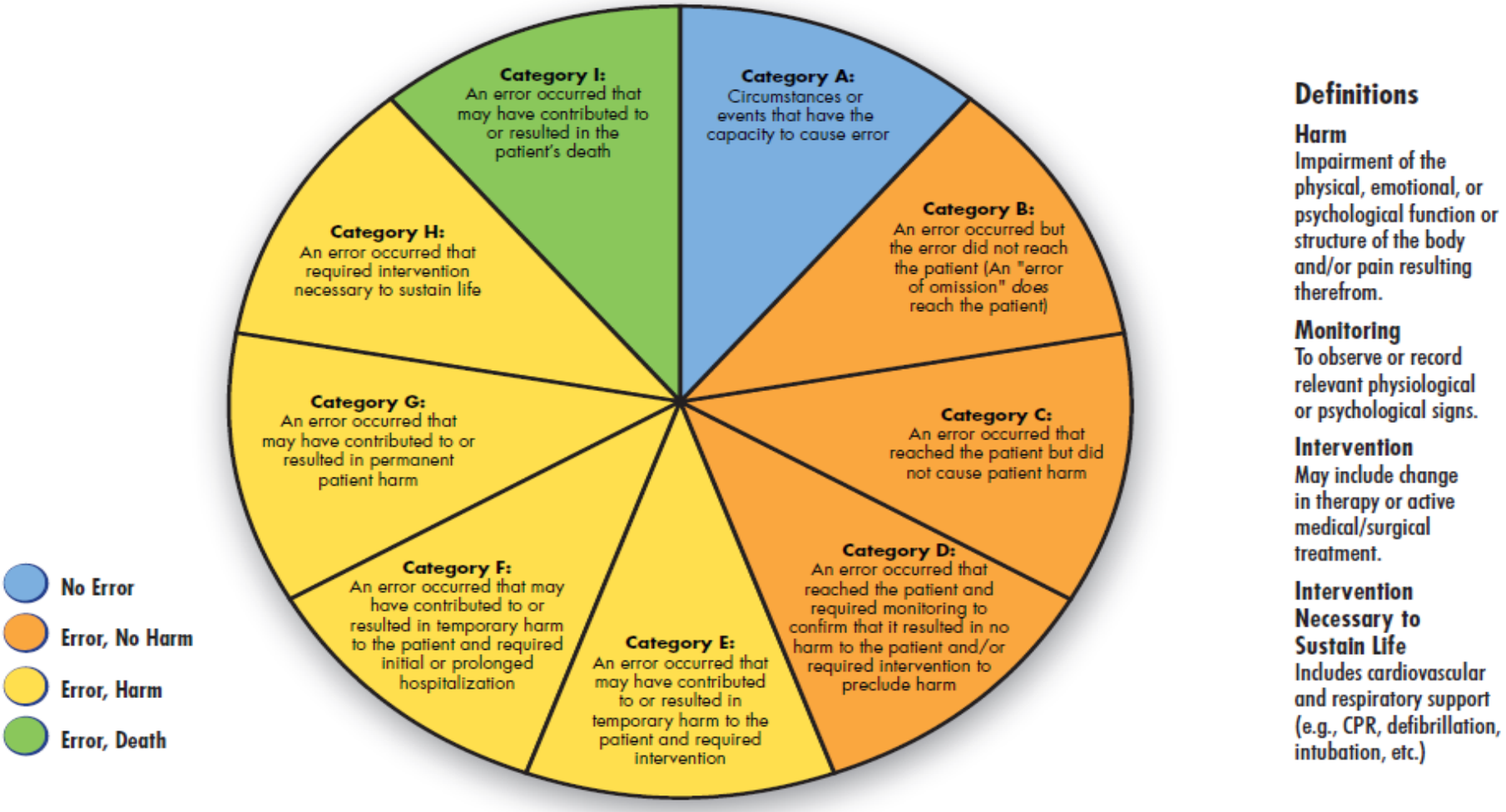

Figure 1.9. Index for categorising medication incidents (from NCC MERP, 2001, p.1)

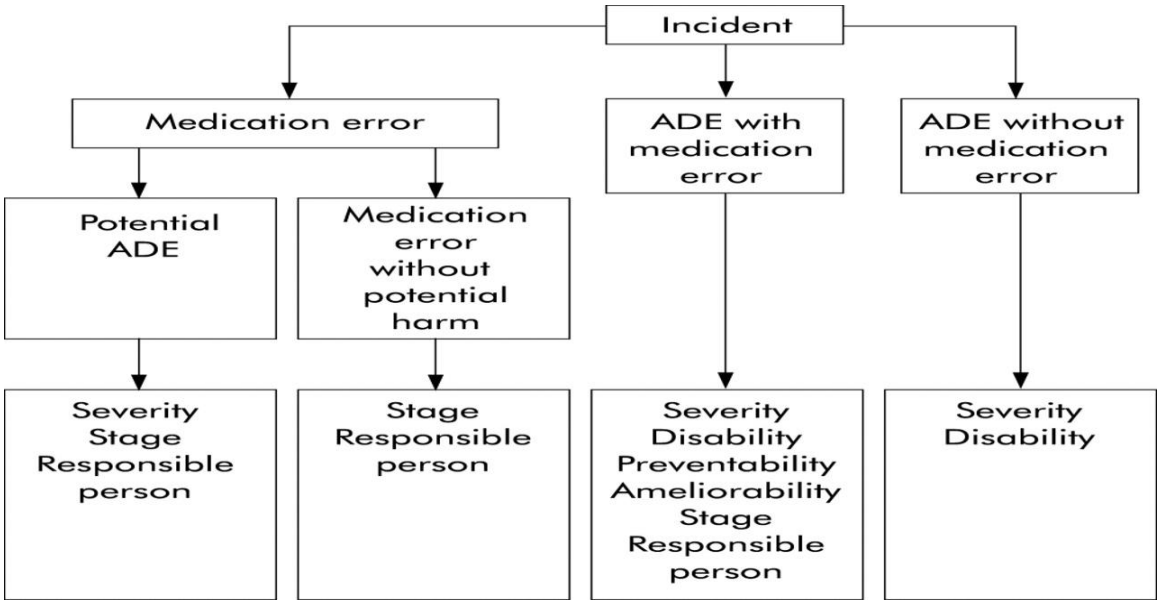

Figure 1.10. Flow diagram to classify the incidence of adverse drug events (ADEs) and medication errors (from Morimoto et al. 2004, p 312)

1.9. Nurses training on medicine administration and double checking

Nurses and midwives in England, Wales, Scotland and Northern Ireland must register with the Nursing and Midwifery Council (NMC) which is considered the regulator for nursing and midwifery practice in the UK. Degrees in nursing are offered by a large number of universities across the UK. Currently, 1000 programmes in 79 institutions are accredited by NMC across the UK (Nursing Midwifery Council 2016). These programmes must consist of at least three years and include at least 4,600 hours of contact time. NMC set training and education standards, requirements, and guidance for these institutions. These standards state the competences and outline the design and contents of education programmes (Nursing and Midwifery Council 2016, Nursing Midwifery Council 2016). NMC accredit education institutions and programmes and provide quality assurance of their approved programmes. When nurses and midwives successfully completed their courses, NMC is responsible for registration.

Table 1.8. Examples for strategies for reducing incidents of different psychological classes of medication errors (Ferner and Aronson, 2006, p.8-9)

Potential strategy for avoiding error	Stage of treatment process	Examples
Knowledge-based errors	Deciding to treat	Being unaware of value of sodium bicarbonate in amitriptyline poisoning
Improved teaching; computerised decision-support systems	Writing the prescription	Being unaware of the interaction between warfarin and azapropazone
	Dispensing the medicine	Failing to know that chloroform and chloroform water are different
	Preparing for administration	Not knowing that paraldehyde dissolves plastic syringes
	Administering the medicine	Being ignorant of the course of the sciatic nerve
	Monitoring the treatment	Taking blood for lithium concentration into a heparin tube, unaware that it contains lithium heparin
	Adjusting or ceasing treatment	Continuing after 2 weeks to give amiodarone at the loading dose
Rule-based errors: misapplying a good rule	Deciding to treat	Instituting cardiac massage in a patient who has fainted
Improved teaching; computerised decision-support systems	Writing the prescription	Prescribing oral treatment in a patient with dysphagia
	Dispensing the medicine	Withholding necessary treatment while checks are made
	Preparing for administration	-
	Administering the medicine	Giving an intramuscular injection of diclofenac into the thigh
	Monitoring the treatment	Taking a blood sample at the time of trough lithium concentration
	Adjusting or ceasing treatment	Giving a short course of antibacterial treatment
Rule-based errors: applying a bad rule or failing to apply a good rule	Deciding to treat	Prescribing amoxicillin for sore throats
Systematic examination of and improvement to rules	Writing the prescription	Printing drugs chart without space to record allergies
	Dispensing the medicine	Dispensing intravenous vincristine and intrathecal methotrexate together
	Preparing for administration	Using multidose vials
	Administering the medicine	Not taking alendronate tablets with water
	Monitoring the treatment	Monitoring for agranulocytosis when giving carbimazole
	Adjusting or ceasing treatment	Prolonging antibacterial treatment unnecessarily

Table 1.8: (Continued) Examples for strategies for reducing incidents of different psychological classes of medication errors (Ferner and Aronson, 2006, p.8-9)

Potential strategy for avoiding error	Stage of treatment process	Examples
Action-based errors (slips)	Deciding to treat	-
Increased checking systems to detect slips; increased 'triangulation' when drug, patient and condition are specified; increased use of unique identifiers or barcodes	Writing the prescription	Distractedly writing chlorpropamide for chlorpromazine
	Dispensing the medicine	Dispensing 5mg vials of vincristine in place of 1mg vial
	Preparing for administration	Drawing up dopamine, not doxapram
	Administering the medicine	Injecting into an intravenous cannula a drug intended to be given by nasogastric tube
		Making a warfarin clinic appointment for 3 months, not 3weeks
	Monitoring the treatment	Stopping warfarin treatment after 3 months for recurrent deep vein thrombosis
	Adjusting or ceasing treatment	
Technical slips	Deciding to treat	-
Checklists; computerised reminders; 'fail-safe' systems	Writing the prescription	Writing illegibly, so that 'Daonil®' (glibenclamide) is dispensed for amoxicillin
	Dispensing the medicine	Dispensing the wrong strength or concentration of drug
	Preparing for administration	Failing to mix infusion to which potassium was added
	Administering the medicine	Giving intravenous injection extravascularly
	Monitoring the treatment	Failing to measure blood pressure correctly[55
	Adjusting or ceasing treatment	Failing to switch off an intravenous giving set
	Deciding to treat	Forgetting that the patient is allergic to penicillin
Memory-based errors (lapses	Writing the prescription	Omitting a date on which to stop treatment
Increased skills training	Dispensing the medicine	Leaving a bottle of tablets on the counter when dispensing
	Preparing for administration	Forgetting to wipe the rubber septum of a drug vial
	Administering the medicine	Forgetting to check the allergy wristband
	Monitoring the treatment	Forgetting to arrange a warfarin clinic appointment
	Adjusting or ceasing treatment	Forgetting to stop clopidogrel treatment after 12 months

Nursing students spend half their time in the classroom and half in clinical settings, where they can practice nursing and gain real experience of patient care including medicines administration (Nursing Times 2016). Nursing students training allows them to practice in a 'real' environment, to extend their skills in different clinical areas (Nursing Midwifery Council 2016). While in training, and in order to achieve registration standards, students are given opportunities to practice medication administration under direct supervision of a registered nurse/midwife, who will be held accountable for the student's practice. Since April 2016, nurses and midwives are required to revalidate their registration every three years. This revalidation replaced the post-registration education and practice (PrEP) requirements which finished on 31 March 2016 (Nursing and Midwifery Council 2016).

NMC standards for nurses' competence consider medicines management one of the five essential skills clusters that have to be reflected in nurses learning outcomes. As part of their competencies in safe practice, nurses must prove that they aware of the safe use and hazards of medicines calculation and administration including the required skills for medicines management, calculation, and monitoring for infants and children for children's nurses. The program providers must ensure that pharmacology and medicines management is included in the content of nurses' education programs and that the program content enables students to meet the essential skills in relation to medicines management (Nursing and Midwifery Council 2010). In addition, the standards emphasised that, by entering to the register, nurses understands and able to apply the knowledge of IV fluids and how they are administered within local policy of administration of medicines. Before entering the register, the newly qualified graduate nurse should demonstrate the skills of basic medicines calculations of all dosage forms including all types of injections and IV infusions together with specific requirements for children and other groups of patients (Nursing and Midwifery Council 2010).

In addition, the standards ensure that nurses learn and work within legal and ethical frameworks with regard to safe and effective medicines administration in practice including statutory requirements for controlled drugs, mental health, mental capacity, children and young people. The standards also emphasis that nurses and before they entry to the register have a comprehensive knowledge of basic pharmacology, mechanism of action, drug-drug interaction and side effects of commonly administered

medicines as well as knowledge on management of ADEs, ADRs, prescribing and administration errors in order to safely manage drug administration and monitors unwanted effects (Nursing and Midwifery Council 2010).

After registration, some Trusts have approved training and competencies for medicines preparation and administration and nurses need to meet these approved competencies before administering medicines. In addition, specific training is required for some specific groups of medicines (e.g. IV doses, handling/administration of cytotoxic medicines) are also required (Trust Drug and Therapeutics Committee 2015).

The standards of NMC indicate that IV doses should be checked by two registrants, one of whom should also be the registrant who then administers the medicine to the patient. Independent double checking is also required for some drug administration such as the preparation and administration of controlled drugs, cytotoxic Chemotherapy, intrathecal medicines, and those requiring complex calculations (Nursing and Midwifery Council 2010, Trust Drug and Therapeutics Committee 2015).

1.10. Implications for the present research

There is an inherent risk of harm associated with medicines and research has shown that medication-related incidents account for a large proportion of PSIs in hospitals (Thomas et al. 2002, Nuckols et al. 2007, Morimoto et al. 2010, National Patient Safety Agency 2015). Incidents during the administration stage were also found to represent the majority compared with other stages of the MUP (Ashcroft and Cooke 2006, National Patient Safety Agency 2013). The administration stage is the last stage before the medicine reaches the patient thus incidents at this stage are least likely to be prevented before they reach the patient. Moreover, patients in hospitals receive more administrations than prescriptions, which results in more opportunities for unwanted actions (Cousins et al. 2012). In addition, MIs reports from the UK revealed that the majority of incidents associated with patient harm and deaths occurred during the administration stage (National Patient Safety Agency 2007). Therefore, such data suggest that more efforts are needed to improve the safety of medicine administration by reducing the incidents and harm that may result from such incidents. Understanding the errors is fundamental to achieving such an aim.

1.11. Overall thesis aims

This thesis aims to evaluate the nature and severity of incidents associated with medication administration and to establish the number of reported MAIs to the total number of occupied bed days (OBD), to accurately identify clinical directorates where reporting medication incidents was higher. The thesis also aimed to explore the perceptions of nurses and midwives at an NHS Foundation Trust of contributing factors leading to medication administration incidents and investigate the impact of nurses' fatigue and sleepiness during long night shifts on the error rate and type of IV preparation and administration.

Chapter 2. Assessing the Reporting of Medication Administration Incidents: Retrospective Analysis of Incident Reports Using Bed Occupancy

2.1. Introduction

2.1.1. Medication incidents monitoring

Incident reporting is considered key to monitoring medication safety, which aims to improve patient safety. Failure to learn from mistakes would appear to be one of the barriers to improving patient safety in healthcare systems. Lack of experience exchange between individual health-care providers or health-care organizations is another aspect which can consequently cause the same mistakes to occur repeatedly. Incident reporting with appropriate incident review supports learning and can be used within organisations or across organisations through regional or national reporting systems. Such systems can improve learning from errors and promote sharing experience across a wider base. Therefore, effective reporting systems can be the cornerstone of safe healthcare practice by helping to identify risks, and measuring the progress in achieving a safe culture in healthcare organisations (Leape and Abookire 2005).

The advantage of incidents reporting systems over other systems used for tracking quality and safety, such as audits, retrospective reviews of records, and litigation databases, is that reporting systems provide data directly obtained from healthcare providers close to the incident and usually at the time when the incident occurred (Simon et al. 2005).

A draft guideline for AE reporting and learning systems was created by the WHO (2005) to facilitate the development / improvement of incident reporting systems. The guideline recommended that to be successful, reporting systems should be non-punitive; confidential; independent; expertly analysed; timely; systems-oriented; and responsive (Leape and Abookire 2005).

2.1.2. Characteristics of successful reporting systems

As mentioned by Hua and Gong (2011) in their review of the design of effective voluntary incident reporting systems, many factors can influence the acceptance and usage of effective systems. Factors such as legislation, leadership support, blame and punitive culture, clinician involvement, and system usability play a role in the quantity and quality of incident reporting systems data. The review also revealed that challenges in the design of reporting systems, such as voluntariness, terminology/taxonomy,

availability of a blame free culture, a positive reporting culture, usability and utility concerns, and feedback provision have an impact on the quality of reports submitted to the system.

The WHO guideline for AEs reporting and learning systems (2005) published the essential characteristics for any reporting system to be successful. These characteristics involved: non-punitive, confidential, expert analysis of reports, timely analysis and reporting, systems-oriented, and responsive in terms of disseminating and implementing recommendations. The same guideline added additional requirements that should be considered carefully before establishing a national reporting system. These were:

- Clear objectives;
- Clarity about who should report;
- Clarity about what should be reported;
- Mechanisms for receiving reports and managing data;
- Expertise for analysis;
- Capacity to respond to reports;
- A method for classifying and making sense of reported events;
- The capacity to disseminate findings;
- Technical infrastructure and data security (Leape and Abookire 2005 p53).

Four main components should be available in order to create an effective reporting system as identified by the Agency for Healthcare Research and Quality (AHRQ) (2012). These include: a supportive environment in the institution which protects the privacy of the reporter, receiving reports from a broad range of departments and professions, regular dissemination of reported events summaries, and presence of structured plans to analyse reports and develop action plans.

2.1.3. International reporting of medication incidents

Different national reporting systems have been established to improve patient safety. These reporting systems vary in sponsorship, support, participation, and function. Some were developed by governmental agencies such as those in England and Wales, Denmark, the Czech Republic, and Sweden. Others such as the Australian Incident Monitoring System (AIMS) have been developed within the private or non-government sector (Leape and Abookire 2005). In the US, there is no governmental reporting

system; however 21 of the 50 state governments have been operating mandatory reporting systems for decades. Reporting unexpected deaths is mandatory in all 21 systems and reporting wrong-site surgery in many systems. Non-governmental national reporting systems include MedMARx, a database maintained by the U.S. Pharmacopeia, the Institute for Safe Medication Practices (ISMP) and the Joint Commission (Leape and Abookire 2005).

2.1.4. National reporting of medication incidents

2.1.4.1. England and Wales

Within the NHS, patient safety has become an important issue, particularly in the past 15 years. This was because of the increased concerns about patient safety incidents which lead to preventable harm. Improving patient safety by learning from these incidents was also emphasised by the DoH in their report (2000) "An Organisation with a Memory" which highlighted a number of recommendations to facilitate and encourage different PSIs reporting.

In 2001, DOH published the report, "Building a safer NHS", which provided an action plan to implement specific patient safety recommendations in the UK. These recommendations included the establishment of the NPSA (Department of Health 2001). The NPSA is a national independent system aiming to improve patient safety in NHS trusts in England and Wales (National Patient Safety Agency 2015).

In 2003, NRLS was established by the NPSA to become a national database for PSIs. The aim of the NRLS is to collect and analyse reports from NHS organisations in England and Wales and also to produce recommendations to build safer systems and reduce risks to patients. Since the establishment of the NRLS, NHS healthcare staff have submitted more than 4 million patients safety related incidents (National Reporting and Learning System 2015). NHS staff can report any patient safety incident confidentially through their local reporting systems. Reporting incidents is recommended whether they result in harm to patients or not. In April 2010, reporting all serious incidents (including death and severe harm) became mandatory for NHS Trusts in England and became an essential for the Care Quality Commission (CQC). The reports are then submitted to the NRLS. Reports are analysed by clinicians and safety experts to identify the frequency, types, trends of incidents, underlying contributory

factors, as well as identifying opportunities to improve patient safety. Healthcare organisations then receive feedback and guidance to improve patient safety (National Patient Safety Agency 2013). These can be:

- Patient safety resources including regular alerts, guidance, data reports, and tools to build a strong safety culture.
- National campaigns on specific topics (e.g. clean your hands, patient safety first).
- Conducting global campaigns and initiatives through collaboration with international organisations to provide comparative incident data to organisations and release alerts and safety signals of potential risks.

From 1st January 2012, the NPSA patient safety key functions have transferred to the NHS Commissioning Board Special Health Authority (the Board Authority) to ensure developing patient safety improvement and address patient safety issues (National Patient Safety Agency 2015). The Medicines and Healthcare products Regulatory Agency (MHRA) is an agency which was established in 2003. Its role is to ensure a safe use of medicines and medical devices. MHRA operates a pharmacovigilance system to investigate and monitor ADRs. In order to enhance the quality of reporting and learning from medication incidents and ADRs, a partnership between NHS and the MHRA was started. As part of this strategic partnership, NRLS became responsible for MIs reporting while ADRs are reported to MHRA using the Yellow Card Scheme (Figure 2.1) (NHS England 2014).

2.1.4.2. Northern Ireland

The Northern Ireland Medicines Governance Team was established in 2002 to improve medicines risk management across secondary care in Northern Ireland which then expanded in 2010 to also cover primary care. The aim is to support the delivery of the medicines safety agenda across Northern Ireland. The team is run by pharmacists (Medicines Governance Northern Ireland 2015). The website provides current safety policies, guidelines, newsletters and reports produced by the teams such as "Medication safety matters" to improve learning from reported incidents (Medicines Governance Northern Ireland 2015).

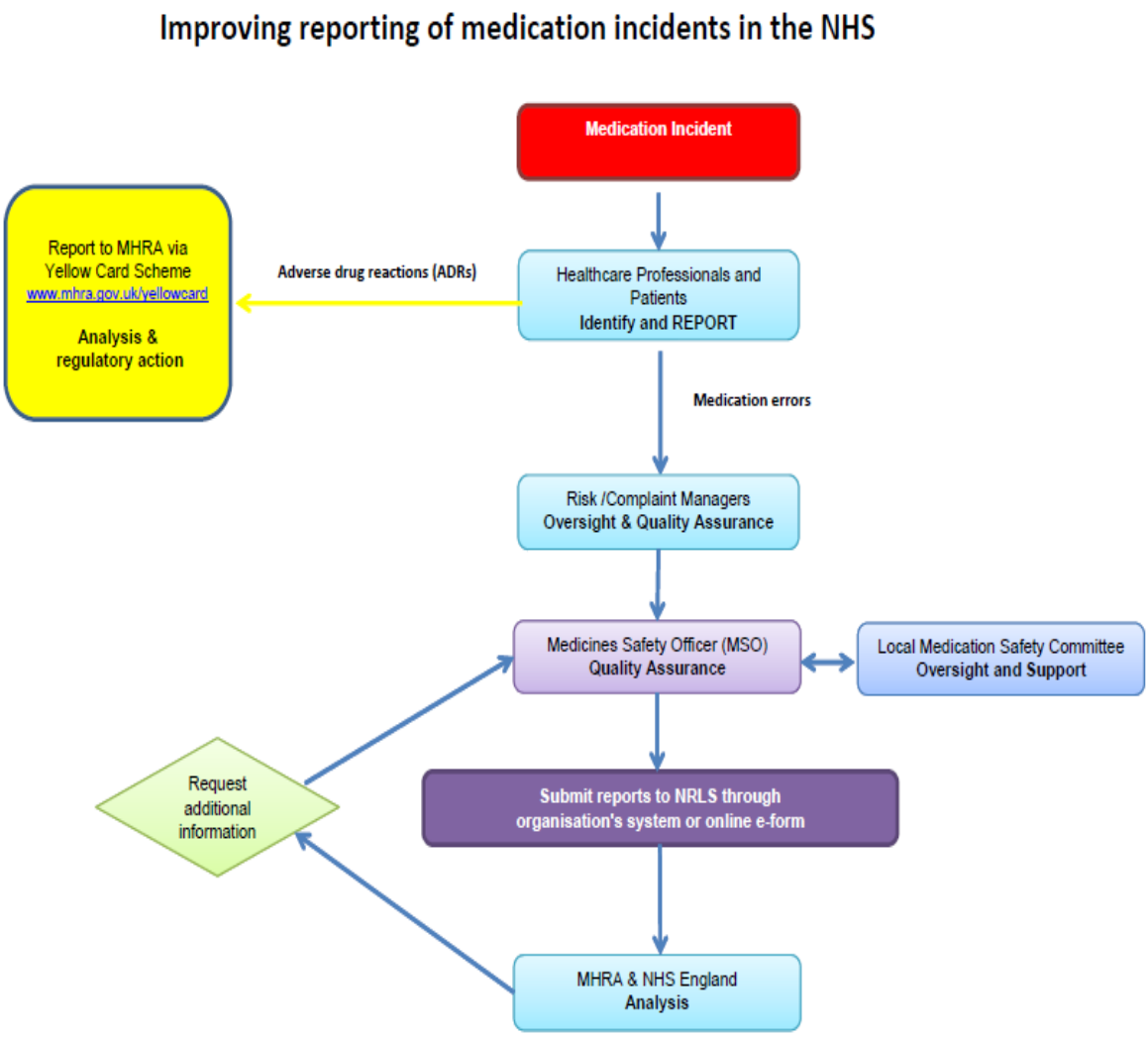

Figure 2.1. NHRA and NHS model for the flow of information needed to improve medication incidents and DRRs reporting in the NHS (National Health Service England 2014, p.4)

2.1.5. Advantages of reporting systems:

The presence of an incident reporting system in hospitals is essential for patient safety monitoring. Although incidents may be underreported, for example due to staff reluctance to report or remembering to report during high workload (Flynn et al. 2002), voluntary reporting is considered a routine method of collecting medication incidents. This is because it is low cost and provides data for all hospital locations over an extended period of time when compared an observational method which has relatively higher cost and only provides data over a selected time period and from specific units

(Allan and Barker 1990, Barker et al. 2002). Incident reporting also allows comparison of incidents between similar units or between sites (Allan and Barker 1990).

Leape (1997) suggested it is essential to determine a baseline for improvement measurement and stated that one of the aims of such initial data is to act as "stable and producible measure of the problems" (Leape 1997 p 216) to evaluate the impact of any implemented interventions to improve patient safety. Therefore, analysing reported incidents and identifying their root causes can be used for learning purposes by providing insight into harmful incidents and help in designing and introducing effective actions, and evaluating the outcomes. Another benefit of incident reporting is the exchanged experiences between different healthcare teams (Vincent and De Mol 2000).

2.1.6. Disadvantages of reporting systems:

Many disadvantages of incident reporting methods have been identified. The main limitation of collecting data using this method is that some incidents may not be reported, resulting in underestimation of incidents (Allan and Barker 1990, Flynn et al. 2002) especially of serious incidents (Shojania 2010). Therefore, the data obtained may not necessarily represent all incidents which occurred during the period studied. This under reporting will affect the quality of data collected and in consequence affect learning from incidents and the patient care improvement possible from such reports. Shojania (2010) suggested that the data obtained from reporting systems was more likely to reflect the changes in reporting patterns rather than changes in underlying risks and therefore, such data cannot track changes in safety. In a study conducted by Cullen et al. (1995) showed that only 6% of 54 ADEs and only 2 of 26 serious/life threatening ADEs that occurred over 6 months were reported.

Another UK study in two maternity units in London identified a serious underestimation of the level of reportable incidents. It was identified that of 196 adverse incidents identified in 500 deliveries, staff reported only 23% of these and another 22% were identified by risk managers. The remaining incidents (55%) were identified only by retrospective case-note review. Furthermore, staff reported only 48% of serious incidents, few of the moderately serious (24%) and minor incidents (15%) (Stanhope et al. 1999). Finally a systematic review of 37 studies from 12 countries to estimate the extent of under-reporting of ADRs, demonstrated that the median under-reporting rate

across all studies was 94% (inter-quartile range 82–98%) with no significant difference between general practice and hospital-based studies (Hazell and Shakir 2006).

Many reasons for underreporting are reported in the literature including the high workload in some locations preventing staff reporting incidents which have occurred, or variations in incident reporting culture among staff. However, the most common reported cause was the fear of any punitive action against the staff member who reported the incident (Allan and Barker 1990, Barker et al. 2002). In addition, discrimination at work place, legal consequences, unfamiliarity with the reporting process, and lack of clarity about reporting purposes could be other barriers to reporting (Mahajan 2010). Evans and colleagues (2006) in a study of barriers for nurses to report PSIs identified that lack of feedback (61.8%), belief that misses did not need to be reported (49%), and forgetting to report due to the increased workload (48.1%) were the main barriers.

2.1.7. Improving incidents reporting

In March 2008, the NHS Confederation together with the NPSA released a statement of five key changes that could be made by organisations to improve patient safety reporting:

Action 1: give feedback to staff

It is important to show the staff that the effort made and the time consumed in reporting PSIs is valuable and used by the organisation to carry out changes to make services safer. Without feedback, reporting can be seen as a useless process, rather than a powerful mechanism for change. It is important to acknowledge the reports through regular feedback and it helps in engaging and motivating healthcare professionals to report. Regular feedback can be delivered through different mechanisms. For example: regular newsletters highlighting incidents which have prompted action; trend analysis, case study reports, providing feedback by central team visits or champions, and discussion of incidents in regular ward level meetings.

Action 2: focus on learning

The main aim of reporting incidents should be to understand and analyse the causes of incidents, learning from them and then take the suitable actions to minimise the hazards, rather than blaming the staff. Incidents reporting can be used to drive local safety

improvements and is important to identify topics or themes which need to be reviewed in-depth. The impact of these changes on the practice and decisions of the organisation should be seen by senior staff and clinicians to sustain good levels of reporting.

Action 3: engage frontline staff

The statements states that high-reporting organisations scored above-average in safety culture rating in Healthcare Commission staff surveys. The survey showed that staff from these organisations knew how to report; felt supported by their organisation, and stated they were receiving feedback about what they reported. Therefore, sufficient training on the 'what, how and why' was identified as key to improve the reporting level and receiving meaningful and useful data that can be used to generate actions after analysis.

Action 4: make it easy to report

In many high-reporting organisations, the forms designed for reporting were as simple as possible. Using online reporting systems helped increase the consistency and efficiency throughout the reporting process, although paper forms may be still needed in some cases as in busy wards with limited access to computers. Moreover, some organisations also introduced new ways to encourage busy staff to report and save staff time e.g. using a short form on medication trolleys to report medication errors immediately, and providing links in the reporting system to download the patient and staff information details automatically from the central records.

Action 5: make reporting matter

In organisations with high reporting rates, the boards and senior managers illustrated strong and visible safety leadership. This was an indication of investment in a robust system and use of information obtained from reported incidents to support decision making at the highest level of the organisation (National Patient Safety Agency 2008).

A survey conducted by the UK National Audit Office (2005) showed an increase in the annual reporting rate of incidents to trusts' incident reporting systems. It was suggested that this change was because of the progress made by trusts in creating a reporting culture. From 2001-2002 until the report was published in 2004-2005, reporting increased by 24%. The survey also found that 78% of 256 trusts involved in the survey,

found that their encouragement of staff to report PSIs resulted in a positive impact on the number of PSIs reported. However, trusts acknowledged that incidents were still under reported. It was estimated that 22% of incidents and 39% of near misses were underreported. Nonetheless, the underreporting of near missed was probably because of the differences between staff understanding of what was considered a near miss (National Audit Office 2005).

2.1.8. Reporting of medication incidents

The reported rates of MEs varied between studies which may result from different study settings, date, adopted definitions, and methods used to identify MEs. Moreover, different baseline and denominators have been used to calculate the rate of errors (Allan and Barker 1990, Keers et al. 2013, McLeod et al. 2013).

In England and Wales, over six years (2005 to 2010) reported MIs accounted for 9.68% (n=526, 186) of all PSIs (Cousins et al. 2012). In 2011 and 2012, the proportion of MIs remained high and was the second most common type of incidents reported and accounted for 11.4 (n=149,409) and 11.1% (n=158,951) respectively. In 2013 it was the third highest PSIs, representing 11% of all reported incidents (n=175,406) (National Patient Safety Agency 2013). In the US, an analysis of 3,875 randomly selected incident reports from three voluntary reporting systems in two US hospitals showed that MIs were the most common reported incidents, accounting for 29% (n=1094) of all reports (Nuckols et al. 2007). In an Australian study, the incident reports collected by the AIMS showed that until 2002, MIs represented 26% (n=7,155/27,000) of all incidents reported in hospitals. In addition, a voluntary anonymous system which was established to collect incidents in general practice in Australia reported that 50.1% (n=1294) of 2582 reports were medication-related (Runciman et al. 2003).

2.1.9. Reporting of medication administration incidents

Studies from the UK showed that MI reports during administration stage were higher than other stages of the MUP (Ashcroft and Cooke 2006, Alrwisan et al. 2011, Cousins et al. 2012). Studies that analysed medication related incidents reported by hospital staff showed that the proportion of administration incidents varied between 46.5% (Ashcroft and Cooke 2006) and 59.3% (National Patient Safety Agency 2007). Ashcroft and Cooke (2006) analysed MIs reported to an online reporting system in a large teaching

hospital (1000 beds) and found that 46.5% of the 495 submitted incident reports were related to medication administration. In Cousins's (2011) report of medication related incidents submitted to the NRLS between 2005 and 2010, administration incidents (50.0%, n=263,228) represented the majority of reports.

In US studies, the proportion of reported incidents during administration stage was slightly lower than prescribing (Bates et al. 1995, Leape et al. 1995, Kopp et al. 2006). Using patients' records in two hospitals, Leape and colleagues (1995) identified that 39% (n=130) of 334 errors occurred during the prescribing stage, and 38% (n=126) in the administration stage. A retrospective analysis of incident reports conducted in a general hospital in Brazil revealed that 64.3% of 230 reported incidents occurred during the medication preparation and administration stage (Silva et al. 2011). As medication incidents are associated with all stages of medication use, all types of patients, and the majority of medicines, identifying incident types which are reported more frequently and cause greater harm is essential to improving the safe use of medication (McLeod et al. 2013).

The denominator used in medication error studies is considered a potential problem in quantifying and comparing error rates. The denominator used is not stated in some studies, while some studies did not specify if more than one error can occur in one dose and therefore the percentage of error rate exceeded 100 (Tully and Franklin 2015). Different denominators have been used in ME studies to calculate the error rate. Studies of prescribing errors commonly reported errors rates per medication order, per admission (commonly per 100 admissions), or per patient day (commonly per 100 patient day) (Lewis et al. 2009). A less commonly used denominator of prescribing errors is prescription chart (Bacic Vrca et al. 2005). In dispensing error studies, the number of items dispensed, number of prescriptions (Anacleto et al. 2007), or number of doses (Ambrose et al. 2002, James et al. 2009) were the most commonly used denominators. In studies of MAEs, direct observation is the most commonly used method and therefore the total number of observed doses was commonly used as a denominator. Most incident reports studies reported the overall number of incidents and have not used any denominator to compare the rate of reported incidents between different clinical areas (Ashcroft and Cooke 2006, Alrwisan et al. 2011, Cousins et al. 2012). Although number of admissions is commonly used by the NPSA as a

denominator to compare incidents reporting between different trusts, the NRLS updated the denominators used to calculate reporting rates and compare different organisations. Since April 2014 the NRLS started using the average daily overnight bed occupancy to calculate the incident rates which is believed to better reflect the individual's exposure to risk.

2.2. Aim and objectives

2.2.1. Study aim

The aim of this study was to analyse the types, drugs involved and severity of patient harm associated with MAIs and then use the data collected from the hospital reporting system to compare the number of reported MAIs to the total number of OBD to accurately identify clinical directorates where reporting was higher.

2.2.2. Study objectives

The main objectives of this study were to:

1. To identify the proportion of MAIs of the total number of reported incidents in all stages of the medication process.
2. To identify the most common types of reported administration incidents.
3. To analyse the reported severity of different types of administration incidents
4. To identify the drugs involved in the administration incidents.
5. To compare the reporting of MAIs to the total number of occupied bed days (reported incidents per 1000 patients days) in each clinical directorate to determining the areas where the MAIs reporting appears higher.

2.3. Methods

2.3.1. Study design and settings

This retrospective and quantitative study was undertaken using medication related incidents reported to the trust's electronic incident reporting system (Datix®) in one large teaching acute trust. The Trust has an overall capacity of 1100 beds and provides secondary care and receives tertiary referrals for many medicine and surgery sub-specialities including paediatrics, cardiothoracic, cancer, elective orthopaedic and adult and paediatric renal patients (Guy's and St Thomas' NHS Foundation Trust 2015). Medication administration incidents in the Trust reported to the trust's electronic incident reporting system (Datix®) in the 12-month period from April 1, 2011 to March 31, 2012 were identified and analysed.

In addition to the MAIs in each clinical directorate, the total number of OBDs in each clinical directorate in the hospital during the study period was obtained from the hospital informatics department. This was to compare the number of MAIs reported per 1000 patient days in different clinical directorate to accurately identify clinical directorates where reporting of MAIs was higher.

2.3.2. Definitions

This study used the NPSA definition of MEs. The NPSA defined medication errors as:

"Any incident where there has been an error in the process of prescribing, dispensing, preparing, administering, monitoring or providing medicines advice, regardless of whether any harm occurred or was possible" (National Patient Safety Agency 2007 p9).

An occupied bed day for wards open overnight was defined as "one which is occupied at midnight on the day in question". For wards open during the day only, an occupied bed-day is defined as a "bed in which at least one day case has taken place during the day".

2.3.3. The incident reporting system

Datix® is web-based patient safety software for healthcare risk management application. It is used in the study Trust to report all AEs occurring in any setting within the Trust. In the Trust, the predominant aim of the incident reporting system is to improve the safety of patients, staff, and visitors.

Based on the Trust Adverse Incident Policy (Trust Drug and Therapeutics Committee 2015), all observed MIs must be reported, whether or not they are likely to harm the patient. Any staff member can enter and use the system if he or she encounters an incident and the reporter can remain anonymous as provision of a name is not mandatory. If the incident type selected in the form is "medication", the incident is then categorised as a MI. Once the incident is reported on the reporting system, the appropriate manager is notified. The relevant manager reviews the incidents. This is because involving the manager provides more concise and succinct entries and better judgment on the severity harm scale (Trust Drug and Therapeutics Committee 2015).

2.3.4. Classification of medication incidents

Medication incidents reported to Datix® were classified into six main categories: prescribing incidents, incidents during preparation of medicines/dispensing in pharmacy, administration incidents, incidents relating to failure of systems for management of drugs, incidents during drug monitoring or follow up, and incidents occurred during advice (i.e. wrong or poor communication between clinical staff or clinical staff and patients).

MAIs were categorised into fifteen types. Descriptions of some of these incidents can be found in Table 2.1. Dose omission and delayed administration were combined as one category as the distinction is only the duration of the delay.

2.3.5. Ethical considerations

This retrospective analysis did not require Research Ethics approval as it was considered an audit. The extracted data excluded any personal information or confidential patient data. Furthermore, there was no direct contact with patients.

Table 2.1. Details of medication administration incidents categories

Incident type	Description
Dose omission and delay	An Omission was failure to administer the dose before the next dose is due. Delayed was administration more than two hours after the time the dose is due
Wrong frequency	The frequency of doses administered to the patient exceeded or lower that the prescribed.
Wrong infusion rate	The infusion rate of IV doses was higher or lower than prescribed
Documentation failure	The medicine was given but not signed for, or documentation of doses administered in the patient notes made by nurses was inadequate (i.e., no documentation about whether medicine was given, whether the right medicine and was given, or whether the medicine was given at the right time).
Incorrect medication storage	Medication incorrectly stored during drug administration (problem with storage and supply within the ward)
Wrong administration route	E.g. central vs. peripheral line.
Labelling errors	Omitted label or incorrect information provided on the label
Mismatch between patient and medicine	Medication given to the wrong patient.
Wrong preparation method	Using wrong diluents, or preparing the wrong concentration
Medication administered without completed prescription	E.g., prescription not signed or associated with incomplete information about the prescribed medication

2.3.6. Inclusion and excluded criteria

All medication-related incidents submitted to Datix® during the 12 month study period (1st April 2011 to 31st March 2012) were included in this analysis regardless of age, speciality, or location. Reports related to self-administration incidents, incidents outside Trust settings (including outpatients) were excluded. ADRs that occurred when the drug was used as intended (not from error) were also excluded.

2.3.7. Data collection and processing

2.3.7.1. Data extraction

Medication-related incidents reported in the period of the study were extracted from the reporting system by the medication safety consultant pharmacist in the study hospital and exported to Microsoft Excel® spreadsheet. For each medication incident, the data extracted included: the date of the incident, date of reporting, and stage of the MUP in which the incident occurred including administration or supply of a medicine, prescribing, preparation or dispensing in pharmacy, system for management of drugs, monitoring or follow up of medicine use, or advice. Medication incident type (subcategories of administration incidents only such as: omission or delay, wrong dose, or wrong frequency, etc.), the name of the drug involved, location or department in which the incidents occurred, the written description of the incident, investigation, and the level of harm as scored by the reporter were also extracted. Access to the extracted data was limited to the research team. Data on the Excel spreadsheet were then filtered and each incident category (prescribing incidents, dispensing, administration, etc.) exported to a separate spreadsheet. In the next stage, the category of administration incidents was filtered and each subcategory (omissions, wrong dose, wrong medicine, etc.) was extracted into a separate spreadsheet for analysis.

2.3.7.2. Data cleansing

Before analysing the data, the description of each MI was reviewed by the researcher and a medication safety consultant pharmacist to assure the quality and consistency of data. Reclassifying medication incident stage, type, or harm severity was performed if required, especially for MIs classified as "other". Thirty-one reports under the category of "other medication administration incidents" were reviewed and reclassified into the relevant categories. In addition, reports not fulfilling the inclusion criteria were excluded.

2.3.7.3. Data analysis

Quantitative analysis was performed using Microsoft Excel 2007. All data were filtered by the stage of MUP using Excel filters. The total number and percentage of medication incidents at each stage of the MUP were calculated. MAIs were exported to a separate spreadsheet for further analysis. Excel filters were also used to count each type of MAIs (Datix® categorise each incident into one of 24 incidents types e.g. omission, wrong

dose, wrong time). Drugs involved in MAIs were categorised according to the British National Formulary (BNF) 2012 and then the percentage of each BNF class and individual drugs was calculated. The rate of MAIs per 1000 OBDs was determined in each clinical directorate using the data obtained from the hospital informatics department. The number of MAIs per 1000 patient days in each clinical directorate was calculated using the following equation:

$$Rate\ of\ MAIs\ per\ 1000\ patients'\ days = \frac{\text{number of MAIs reported in the clinical directorate x 1000}}{\text{total number of the occupied bed days of the clinical directorates}}$$

The level of patient harm of each MAI was determined by the person who reported the incident and according to the classification of the reporting system of the incident severity which is based on a national classification. The trust's electronic incident reporting system categorises the level of harm as 'no harm' 'low' 'moderate' 'severe' or "death" (National Patient Safety Agency 2007). Table 2.2 describes the definition of each term. The Incident Reporting system provides information to help grade the extent of harm. In addition, the manger reviewing the incident is asked to verify this harm score.

Table 2.2. NPSA definitions of degrees of harm (National Patient Safety Agency 2007, p.54)

Harm	Definition
No harm	Impact prevented: any patient safety incident that had the potential to cause harm but was prevented, resulting in no harm to the person(s) receiving NHS-funded care. Or: Impact not prevented: any patient safety incident that ran to completion but no harm occurred to the person(s) receiving NHS-funded care.
Low	Any patient safety incident that required extra observation or minor treatment, and caused minimal harm to the person(s) receiving NHS-funded care.
Moderate	Any patient safety incident that resulted in a moderate increase in treatment, and which caused significant but not permanent harm to the person(s) receiving NHS-funded care.
Severe	Any patient safety incident that resulted in permanent harm to the person(s) receiving NHS-funded care.
Death	Any patient safety incident that directly resulted in the death of the person(s) receiving NHS-funded care.

2.4. Results

Over the study period, 2,016 medication incidents were reported to the reporting system. Of these, 127 incidents were excluded leaving a total of 1889 reported medication incidents for inclusion in this study. Incidents excluded involved 32 medication incidents occurring before 1st of April 2011 but reported at a later date falling within the specified period, 42 incidents classified as an ADR, 25 medication incidents occurring outside the hospital setting, 27 medication self-administration incidents, and one incident was excluded as insufficient description was provided. During data cleaning, 25 MAIs were reclassified as prescribing, dispensing, or system failure incidents (Figure 2.2).

2.4.1. Medication incidents in different stages of the medication use process

Details of reported MIs in different stages can be found in Figure 2.2. Of the total number of medication incidents analysed, the most frequently reported stage was administration (49.6%, n=937/1889) followed by prescribing (27.8%, n=525/1889), and preparation in pharmacy or dispensing incidents (10.6%, n=200/1899).

2.4.2. Medication process and level of harm

The level of harm was reported in 98.2% (n=1855/1889) of all medication incidents. The majority of reported MIs in all stages (80.3%, n=1516/1889) did not cause any harm to the patient, and 16.9% (n=320/1889) were categorised as low harm (Table 2.3). Only 1% (n=19/1899) were associated with moderate harm. Incidents with moderate harm were associated with administration, prescribing, and dispensing incidents only. No incidents resulted in severe harm.

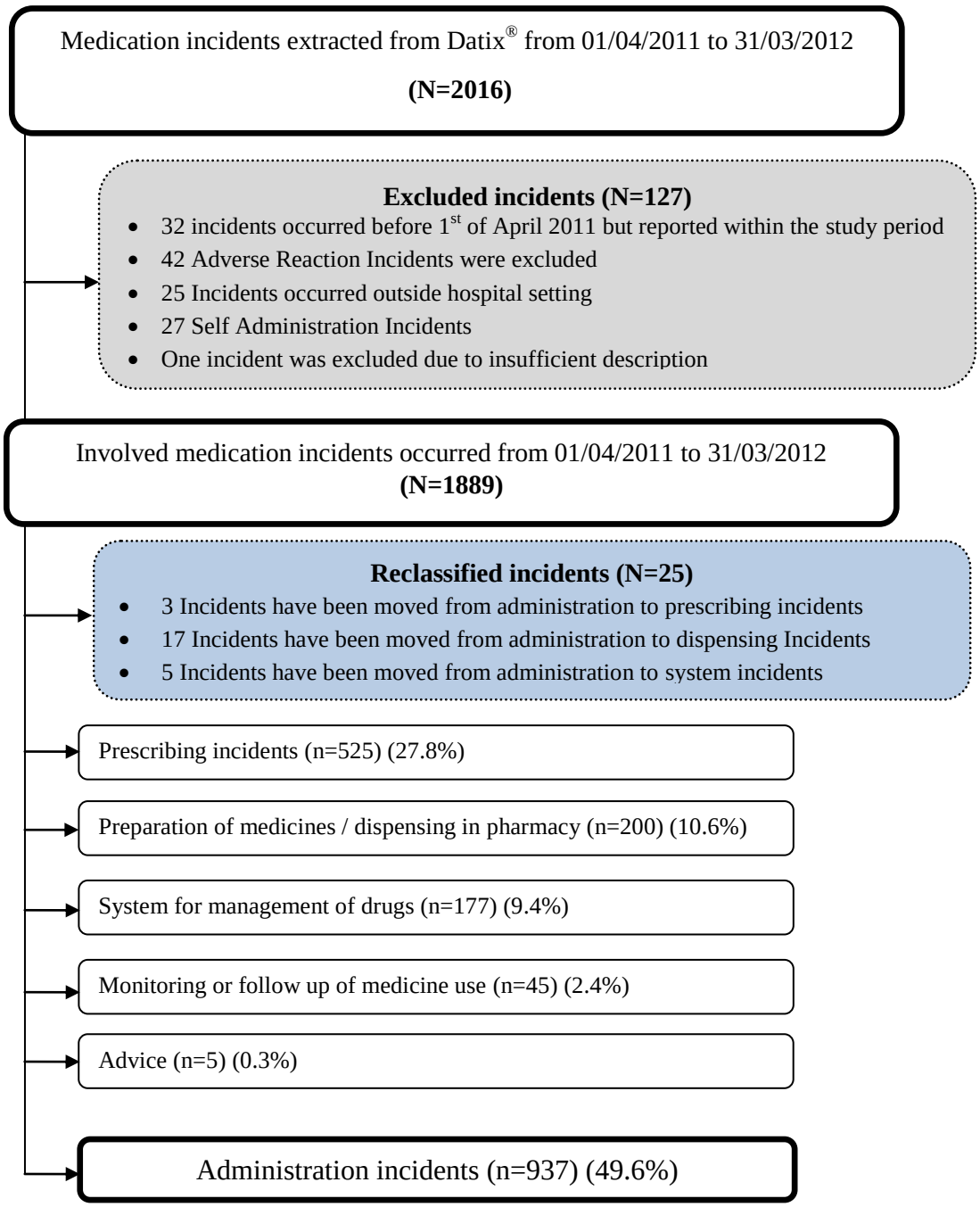

Figure 2.2. The distribution of medication incidents in different stages

Table 2.3. Medication Incidents in Different Stages and Level of Harm (N=1889) [a]

Stage of Medication Use	Total	No Harm	Low Harm	Moderate Harm	Not Specified
	N (%)	N (%)	N (%)	N (%)	N (%)
Administration of a medicine	937 (49.6)	694(74.1)	202 (21.6)	10 (1.1)	31 (3.3)
Prescribing process	525 (27.8)	440 (83.8)	77 (14.7)	6 (1.1)	2 (0.4)
Dispensing/ preparation in pharmacy	200 (10.6)	177 (88.5)	20 (10)	3 (1.5)	0
System for management of drugs	177 (9.4)	168 (94.9)	8 (4.5)	0	1 (0.6)
Monitoring or follow up of medicine use	45 (2.4)	33(73.3)	12 (26.7)	0	0
Incidents occurring during advice [b]	5 (0.3)	4 (80)	1 (20)	0	0
Total	**1889 (100)**	**1516 (80.3)**	**320 (16.9)**	**19 (1)**	**34 (1.8)**

[a] No incidents caused severe harm or death
[b] These incidents included wrong or poor communication between staff**.**

2.4.3. Reported administration incidents

Among reported MAIs, the level of harm was reported in 96.7% (n=906/ 937). Almost three-quarters of reported incidents occurred during the administration stage with severity reported caused no harm (74.1%, n=694/965); followed by incidents resulted in low harm with 21.6% (n=202/937). Ten incidents were associated with moderate harm (1.1%, n=10/937) which accounts about half (52%, n=10/19) of incidents with moderate harm reported in all stages. Details of these incidents can be found in Table 2.4. These incidents were omissions (n=5), wrong dose administration (n=2), wrong infusion rate (n=2), and wrong frequency (n=1). The drug class most commonly involved in administration incident reports with moderate harm was anticoagulants and were involved in four out of 10 incidents (enoxaparin, n=3, and heparin, n=1). Enoxaparin was the most common single drug involved in incidents with moderate harm as it was included in three of the 10 administration incidents (Table 2.4).

Table 2.4. Reported administration incidents with moderate harm and drugs involved (N=10)

Incident Type (N)	Drug involved	Incident details
Medication omission (5)	Enoxaparin	Enoxaparin was signed for but not actually given in the evening and was given the following morning
	Potassium chloride and sodium chloride	Prescribed I.V. fluids (sodium chloride with 40 mmol of potassium chloride) was not given to patient overnight.
	Normal Saline	Patient was very confused since the start of the night shift. Patient found out that his blood test showed avery low sodium level. Upon inspection on the drug chart at 04:00 apparently IV fluid was prescribed, dated ----- but not given by the day staff.
	Tazocin	IVTazocin morning dose not given miscommunication during handover from night to day staff. Drug was not available on the ward at time of due dose. When drug arrived on the ward it was not given immediately due to miscommunication.
	Cyclophosphamide	Cyclophosphamide oral dose (as part of CVD) was "assumption-dispensed" within the pharmacy chemotherapy unit on ----. Dose due (next day) for Cycle 10 Day 1. The Cycle 10 Day 1 IV doses and oral doses were not signed off as 'administered' on the day unit.
Wrong dose (2)	Enoxaparin	The nurse administered 140 mg of clexane instead of 100mg. The nurse mixed the syringe up and made an error by seeing the 0.8 ml on 120 mg syringe and adding a further 20mg.
	Noradrenaline	At 08.45 the noradrenaline pump started to alarm therefore double pumping commenced and the patient was cardiovascularly stable for approx 10 minutes after this. Then approximately ten minutes later the patient became hypotensive with a blood pressure of 60/40. The infusion was increased and the syringes checked. The new syringe was found to be labelled as having 4mg/50ml instead of 16mg/50ml. The patient was stabilised and the noradrenaline weaned back to previous dose. It was unclear whether the label was wrong as the patient remained stable however as another syringe 16mg/50ml was being made up the dobutamine syringe started to alarm. I then stopped to draw up this infusion and changed it. The patient then became hypotensive again. The noradrenaline was increased and the doctors were called, gelofusine was given and the noradrenaline infusion was then changed to a 16mg/50ml infusion and the patients blood pressure increased. Once the patient was stable the noradrenaline was reduced back to its original rate.
Wrong frequency (1)	Enoxaparin	Patient came back at 18.00 from Recovery as handed over.Clexane dose for 18.00 was then given when it supposed to be given at least 6 hours post op. Day staff signature noted but thought it was from yesterday (box). Clexane 40 mg was then given then patient confirmed that she had earlier dose (Patient still drowsy by this time).
Wrong infusion rate (2)	Heparin	Patient receiving IV heparin during day shift -----. APTT result was high at 3.5 and according to protocol IV heparin should have been stopped for 30 min and then restarted at a reduced rate, but was not done. The patient had a small haematoma to L groin existing. The IV heparin was stopped later in the day when the haematoma was found to have increased significantly and patient Hb dropped to 6.2g/dl.
	Syntocinon	Wrong doses given of syntocinon augmentation. Commenced infusion at 3 ml/h at 00:50, increased at 01:20 to 6 ml/h and at 02:00 at 12ml/h. Bbradycardia at 02:13. Baby delivered in good condition by emergency C/S.

2.4.4. Types of reported administration incidents

Reported MAIs were categorised into fifteen types (Table 2.5). The most common MAI type was dose omission and delay (33.5%, n=314/937). The next most common categories were administering 'wrong dose (11.4%, n=107/937), wrong frequency (9.4%, n=88/937), and wrong infusion rate' (9%, n=84/937). These types were followed by administering the wrong medicine, (8.6%, n=81/937), and documentation failure (7.5%, n=70/937).

Other types of MAIs, much less commonly reported, included incorrect medication storage (3.6%, n=34/937), wrong administration route (e.g. central vs. peripheral line) (3.4%, n=32/937), labelling errors (3.2%, n=30/937). Mismatch between patient and medicine (3%, n=28/937); wrong method of preparation (2.8%, n=26/937); wrong formulation (1.7%, n=16/937); medication administered without completed prescription (1.4%, n=13/937); and discontinued medication administered (1.1%, n=10/937) were also reported.

2.4.5. Drugs involved in administration incidents

The drugs involved in MAIs were specified in 96.9% (n=908/937) of reports. Table 2.6 shows the BNF classification of drugs involved in administration incidents. Approximately 4% (n=34/937) of all MAIs involved multiple drug classes (i.e. more than one drug class involved in the same incident). Central nervous system (CNS) agents (30.9%, n=290/937) was the most common drug class involved in reported MAIs, particularly opioid analgesics, which were involved in 17.4% (n=163/937) of all MAIs. The second most common drug class involved was cardiovascular drugs (17.2%, n=161/937) particularly anticoagulants (10.1%, n=95/937) and then anti-infective agents (14.8%, n=139/937). Most anti-infective agent reports involved antibiotics (13.4%, n=126/937).

2.4.5.1. Individual drugs

Morphine was the most common individual drug involved, reported in 9.1% (n=85/937) of all MAIs, followed by enoxaparin (4.9%, n=46/037), insulin (4.6%, n=43/937), paracetamol and fentanyl (4.5%, n=42/937). Details of the most common drugs involved in administration incidents are presented in Table 2.7.

Table 2.5. Types of medication administration incidents and level of harm(N=937)

Type of Medication Administration Incident	Total	No Harm	Low harm	Moderate harm	Not Specified
	N (%)	N (%)	N (%)	N (%)	N (%)
Medicine omitted or delayed	314 (33.5)	200 (63.7)	108 (34.5)	5 (1.6)	1 (0.03)
Wrong dose	107 (11.4)	76 (71)	25 (23.4)	2 (1.9)	4 (3.7)
Wrong frequency	88 (9.4)	68 (77.3)	14 (15.9)	1 (1.1)	5 (5.7)
Wrong infusion rate	84 (9.0)	61 (72.6)	18 (21.4)	2 (2.4)	3 (3.6)
Wrong medicine	81 (8.6)	66 (81.5)	13 (16)	0	2 (2.5)
Documentation failure	70 (7.5)	59 (84.3)	7 (10)	0	4 (5.7)
Medication incorrectly stored	34 (3.6)	32 (94.1)	0	0	2 (5.9)
Wrong route of administration	32 (3.4)	23 (75)	5 (13.9)	0	4 (11.1)
Wrong label	30 (3.2)	26 (86.7)	1 (3.3)	0	3 (10)
Mismatch between patient and medicine	28 (3)	24 (85.7)	4 (14.3)	0	0
Wrong method of preparation	26 (2.8)	21 (80.8)	3 (11.5)	0	2 (7.7)
Wrong formulation given	16 (1.7)	15 (93.8)	1 (6.3)	0	0
Medication administered with incomplete prescription	13 (1.4)	11 (84.6)	1 (7.7)	0	1 (7.7)
Discontinued medication administered	10 (1.1)	8 (80)	2 (20)	0	0
Other MAIs *	4 (0.4)	4 (100)	0	0	0
Total	**937 (100)**	**694 (74.1)**	**202 (21.6)**	**10 (1.1)**	**31 (3.3)**

* Other incidents included: wrong or omitted verbal direction to patient, and patient refused to take medication.

Table 2.6. Analysis of Most Common Drug Classes Involved in MAIs

Drug classes	N	%
Central nervous system agents	290	30.9
Cardiovascular system agents	161	17.2
Anti-infective agents	139	14.8
Nutrition and blood agents	94	10
Endocrine system agents	69	7
Malignant disease and immunosuppressant	24	2.6
Gastro-intestinal system agents	22	2.3
Anaesthesia	15	1.6
Musculoskeletal and join diseases agents	8	0.9
Respiratory system agents	8	0.9
Immunological products and vaccines	7	0.7
Obstetrics, gynaecology, and urinary-tract disorders agents	6	0.6
Multiple classes	34	3.6
Other	31	3.3
Total	**908 ***	**96.4**

* The drug name was not reported for the remaining incidents (n=29).

Table 2.7. Most Common Drugs Involved in Administration Incidents

Drug Name	N	%
Morphine	85	9.1
Enoxaparin	46	4.9
Insulin	43	4.6
Paracetamol	42	4.5
Fentanyl	42	4.5
Heparin	36	3.8
Co-amoxiclav	26	2.8
Gentamicin	26	2.8
Oxycodone	23	2.5
Vancomycin	17	1.8
Midazolam	15	1.6
Warfarin	14	1.5
Cefuroxime	13	1.4

2.4.6. Locations of medication administration incidents

In addition to quantifying the overall number of reported administration incidents, the rate to OBDs for each clinical area was calculated (Table 2.8). The total number of submitted reports was greatest in Children's Services where 22.9% (n=215/937) of incidents occurred followed by Acute Medicine (18.4%, n=172/937); Surgery (13.7%, n=128/937); and Perioperative, Critical Care and Pain (13.3%, n=125/937). The ratio of reported administration incidents to OBDs was highest in Perioperative, Critical Care and Pain directorate (16.9 MAIs reports per 1000 patient days), and relatively similar among Children's Services (3.9 per 1000 patient days) and Surgery (3.8 per 1000 patient days).

Table 2.8. Administration incident rate to OBDs by clinical directorate

Directorate	Number of MAIs (%)	Total of OBDs	MAIs /1000 bed-days
Children's Services	215 (22.9)	55074	3.9
Acute Medicine	172 (18.4)	81792	2.1
Surgery	128 (13.7)	33586	3.8
Perioperative, Critical Care and Pain	125 (13.3)	7402	16.9
Women's Services	88 (9.4)	31462	2.8
Oncology and Haematology	65 (6.9)	31521	2.1
Cardiovascular Services	62 (6.6)	43023	1.4
Abdominal Medicine and Renal Transplant	59 (6.3)	55108	1.1
GRIDA	4 (0.4)	4453	0.9

GRIDA: Genetics, Rheumatology, Infection, Dermatology, and Allergy

2.5. Discussion

In this study, MAIs were found to represent 49.6% (n=965 of 1899) of all MIs submitted to the Trust reporting system over this 12-month period. This is in agreement with previous studies' findings using retrospective incident reporting data which also identified that the administration stage was associated with a higher proportion of incident reports than all other stages of the medication process (Hicks et al. 2004,

Ashcroft and Cooke 2006, Alrwisan et al. 2011). In the UK, Ashcroft and Cooke's (2006) retrospective analysis of MI reports over a 26-month period to in a large teaching hospital (1000 beds) found that 46.5% of 495 submitted incidents were related to medication administration. Furthermore, the UK NRLS identified that reporting MAIs was higher (50.9%) nationally than other stages of medication use (National Patient Safety Agency 2013). In the US, a retrospective study of 42-months in a teaching hospital analysed reported MEs in elderly patients and identified that 54% of 861 errors reported to the hospital's reporting system were administration errors (Picone et al. 2008).

The reporting rates of MIs may vary between studies which may result from the different hospital prescribing and administration systems, settings, dates, definitions and methods used to detect MIs. Moreover, different denominators such as patient days and admissions have been used to calculate the reporting rate of MIs. Therefore, comparisons between different studies of MIs may be limited (Allan and Barker 1990, Ferner 2009, McLeod et al. 2013). In addition, classification of medication incidents into different stages of the medication process varies. Some studies, such as Bates et al. (1993), classified the process into only three main stages: prescribing, dispensing, and administration while other studies (e.g. Bates et al. 1995, Hicks et al. 2004, Lisby et al. 2005, Ashcroft and Cooke 2006, Morimoto et al. 2010, Cousins et al. 2012) classified incidents of monitoring or transcription into separate categories.

2.5.1. Locations of medication administration incidents

Clinical directorates where MAIs reported from were determined in this study. Twenty three percent (n=215) of reported incidents were from Children's Services (neonatology, paediatric surgery, paediatric intensive care, and other paediatric wards) as the most frequently reporting area, followed by Acute Medicine with 18.4% of incidents (n=172).

Most MI studies which used voluntary incident reporting have used overall reporting numbers and have not compared this to the capacity and bed occupancy (Cousins et al. 2012). This is a limitation as clinical directorates with high numbers of patients and therefore high total bed occupancy during the study period might be assumed to be associated with a higher reporting rate of incidents. Conversely, locations with fewer

patient admissions may be incorrectly assumed to be associated with a lower reporting rate of incidents. Hence, weighting by OBDs in each directorate is a useful measure because it corrects for large directorates with high occupancy. It is easily obtained in the UK as all NHS UK hospitals collect their associated OBDs, however few NHS hospitals currently have electronic prescribing and administration, so, data on medication doses administered is not readily accessible.

When the number of reported MAIs to the total number of OBDs was calculated, some directorates which reported fewer incidents appeared to have a higher reporting rate than those reporting greater numbers of incidents. In the current study, Perioperative, Critical Care and Pain directorate was fourth in term of the number of submitted reports, however, when the number of incident reports was compared to the total number of OBDs, Perioperative, Critical Care and Pain became the clinical area with the highest reporting rate of MAIs (16.9 MAI/1000 OBDs) (Table 2.8). Perioperative, Critical Care and Pain had lower capacity and occupancy than other directorates including children services. Again when the number of incidents reported was weighted by total OBDs, Acute Medicine, the second highest reporting directorate (18.4%), became fifth most high reporter. Reported MAIs in Acute Medicine was almost three times higher than in Oncology and Haematology but when weighted by OBDs, the rate of MAIs reported in these clinical directorates was the same (2.1/1000 patients day).

An American cohort study compared ADEs per 1000 patient-days in medical ICUs, surgical ICUs, medical general wards, and surgical general wards and found higher rates of ADEs in medical ICUs (19.4 ADEs/1000 patient-day) compared with other wards (8.9-10.6 ADEs/1000 patient-day) (Bates et al. 1995), indicating a greater medication risk in medical ICUs which is consistent with the current study. This US study determined an incident rate similar to the reporting rate of MAIs in the current study with 19.4 ADEs per 1000 patient-days in ICUs (Bates et al. 1995). However, ADEs exclude incidents which do not cause harm to patients thus rates cannot be compared to our findings where no harm medication incidents dominate. Similar findings were identified in Japan by the Japanese Adverse Drug Events (JADE) study. In this prospective cohort study which involved 3,459 adults admitted to a medical, and surgical wards and three intensive care units in three tertiary care hospitals over 6

months, the identified incidence of MEs in ICU was 17.0 MEs per 1,000 patient-days which was higher than medical and surgery wards (Morimoto et al. 2010).

Many factors may contribute to the increased number of MAIs reported in critical care: with higher patient acuity, more medications are administered (Bates et al. 1995, Kiekkas et al. 2011), and medications used differs as many require calculations during administration especially injections and continuous infusions (Kiekkas et al. 2011).

The routine use of OBD is to be recommended to provide additional information about MAI reporting. The MAI data identified in Table 2.8 can be discussed at clinical directorate and hospital level in order that interventions of proven benefit can be applied. Managers can use weighted medication reporting rate to better understand where risks exist and inform and prioritise allocation of overall patient safety resources. Use of OBD also facilitates comparison between clinical directorates as well. The NRLS in England and Wales uses the incident reporting rate per 100 admissions to compare trusts (National Patient Safety Agency 2013). Weighting by OBD provides additional information to the rate per 100 admissions as weighting by patient admissions is affected by the organisation's length of patient stay which varies over time and between hospitals (National Audit Office 2012).

2.5.2. Types of medication administration incidents

The most common types of reported MAIs were, 'Omitted or delayed doses' and represented around one third of all MAIs (33.5%, n=314) (Table 2.5) followed by 'wrong dose/frequency' (20.8%, n=195). These two types of MAI caused higher levels of harm (8 out of 10 incidents with moderate harm were from these two types). Incorrect frequency occurred when an extra dose was administered to the patient (i.e. the total administered doses exceeded the prescribed daily dose); therefore, wrong frequency and wrong dose were combined as all result in an incorrect dose over 24 hours.

These findings are similar to UK national data and previous studies. Omitted medicine (13%) and wrong dose, strength, or frequency incidents (23%) are commonly reported to UK NPSA (2009). The same NPSA report also showed that 33% of incidents that reported death or severe harm relate to the wrong dose/frequency as the most common

type of incidents associated with severe harm or death (National Patient Safety Agency, 2009). In Ashcroft and Cooke study (2006), incidents of 'wrong dose administration' (36.6%, n=78) and 'omission and wrong timing' (21.6%, n=46) were the two most common reported incidents during administration stage. In Picone et al (2008) analysis for reported MEs in elderly patients in a teaching hospital in the US, omissions and delay (56.1%, n=483) was reported more frequently than other types followed by wrong dose (16.3%, n=140) and wrong drug (10.1%, n=87). In the US also, a descriptive, retrospective secondary analysis of the USP MEDMARX database of MAEs over 5 years identified that 36% of 1305 MEs made by nurse students were omission or wrong timing, and 17.2% were wrong dose administration (Wolf et al. 2006). Barker et al. (2002) also determined in their US observational study on administration errors that omissions and wrong timing represented more than two thirds of observed errors (30% and 43%, respectively,) followed by wrong dose (17%).

The international systematic review of Keers et al. (2013) for observational studies of the prevalence and nature of MAEs also found that wrong time, omissions and wrong dose were the most common MAIs (Keers et al. 2013). Administering the wrong medicine into the patient, which was the fifth most common types of reported incidents after 'omission and delay', 'wrong dose', 'wrong frequency', and 'wrong infusion rate' was also reported in previous studies as the most common type after omissions, delays, and wrong dose administration (Ashcroft and Cooke 2006, Wolf et al. 2006, Picone et al. 2008, National Patient Safety Agency 2009)

2.5.3. Drugs involved in administration incidents

Central nervous system agents were the most frequent drug class reported for all administration incidents in the present study (30.9%, n=290/937). The second class, with a much lower frequency, was cardiovascular agents (17.2%, n=161/937) followed by anti-infective agents (mainly antibiotics) with 14.8% (n=139/937). The UK retrospective study by Ashcroft and Cooke (2006) also found that cardiovascular (27.4%, n=63), CNS (22.6%, n=52), and anti-infective agents (14.8%, n=34) were the most common therapeutic categories associated with MAIs. The medicines involved in reported incidents in the current study are also comparable to those in other observational studies. An international review by Keers et al. (2013) for 91 observational studies for MAEs found that medications in categories of CNS,

cardiovascular system, infections, nutrition and blood, and gastrointestinal system were observed as the five most medication types associated with MAEs. In intensive care units, the groups of cardiovascular, antibiotics, sedatives/analgesics, and electrolytes were the classes most associated with errors as reported in a review of direct observation evidence of MAEs in critically ill patients (Kiekkas et al. 2011).

However, in the retrospective studies, it is not possible to calculate the error ratio of individual drugs or classes to the number of administered doses unless the total number of administered doses or prescriptions is available. Therefore, the high number of reports of some drugs or classes may be referred to their high prescribing rate (Keers et al. 2013). In addition, incidents for some drugs (such as controlled drugs) may be reported more frequently because documentation requirements enhance incident detection.

2.5.4. Severity of medication administration incidents

In the UK, 80% of all MIs reported to NRLS were associated with no harm, 16% low harm, 4% moderate harm, 0.001% severe harm, and only 0.0005% resulted in death as reported by the NPSA (2009). This is comparable to the current study where 74.1% of reported MAIs resulted in no harm, 21.6% resulted in low harm, 1.1% resulted in moderate harm, and none were associated with severe harm or death (Table 2.3). An international systematic review of observational studies of MAIs showed that incidents resulting in no harm or not requiring intervention were most common in studies using the American NCC MERP Index harm categorisation (Keers et al. 2013). However, comparison of severity of harm between studies is difficult because different criteria have been used to describe the extent of harm (Keers et al. 2013). Therefore, to allow comparison across different systems, standardising harm classification is needed.

In the current study, the level of patient harm was determined by the person who reported the incident and according to the classification of the reporting system of the incident severity which is based on a national classification (National Patient Safety Agency 2009) (Table 2.2). Although the Incident Reporting System provides information to help grade the extent of harm through a risk matrix which is used to rate incidents reported to NRLS, rating the level of harm will be based on the individual perception and medical background.

Williams and Ashcroft (2009) evaluated the reliability of the MEs severity rating scale used by the NPSA in England and Wales and the differences among healthcare professionals in the severity ratings. Healthcare professionals involved in the study were given nine scenarios for medication errors on two separate occasions and were asked to use the NRLS severity rating scale to rate the severity of each incident. The study revealed marked variations in the ratings for MIs against the NRLS severity criteria between different health professionals and even within the same individual at different time points.

2.5.5. Quality of information in medication incident reports

One of the issues in incidents reporting systems is the quality of information in the submitted reports which may affect using and analysing the data. This can be influenced by several challenges related to the design and adoption of reporting systems (Hua and Gong 2011, Cousins et al. 2012). A previous research identified the issue of poor information provided in incident reports and showed that reports obtained from existing systems do not even provide the minimum required information to analyse the causes and recovery actions of these incidents. In a study to assess the Australian health care incident reporting systems utility and usage, Thomas et al (2011) found that only 10.7% (n=52) of submitted incidents have sufficient details to classify the aetiology of the incidents and only 59% (n=288) of reports involved sufficient information to classify the recovery actions of the incidents. Furthermore, in England, a report revealed that poor quality of data and non-availability of sufficient details was common in MI reports submitted to NRLS (n=12,355) (National Health Service England 2014).

In the current study, some reports were submitted with poor quality either due to insufficient or incorrect information provided, or due to incorrect classification of incidents into the correct category. For example, 31 (3.3%) MAI reports were submitted without scoring the level of harm, and a further 54 (5.8%) reports were submitted without reporting the drug involved. In addition, the incident type of a number of incidents was inappropriately classified. Although some of these data were obtained by the research team from the description of these incidents, not all descriptions involved sufficient details which left 29 incidents without reporting the involved drug name. This may result from the fact that some field in the reporting system Datix® are not mandatory thus making such essential data mandatory will improve the quality of

information of submitted reports. Therefore, it is important that existing reporting systems are developed to provide high quality information with all essential details to ensure the maximum benefit from submitted reports.

2.5.6. Limitations of the study

With voluntary reporting, an increased frequency of incident reporting does not necessarily reflect a higher rate of incidents but may reflect better detection of incidents, time available to complete reports, ease of reporting, or stronger culture of reporting incidents detected (Hutchinson et al. 2009). Drug administration is the last stage in the MUP, thus some MAIs may not be detected and therefore not reported (Allan and Barker 1990). Countering this, the study hospital has robust mechanisms to detect MAIs, such as monitoring the use of reversal drugs and close physiological monitoring of patients. Moreover, the study hospital is highest reporter of MIs of all NHS acute teaching trusts at 20% more reports than next best acute teaching Trust and double the median number of incident reports of acute teaching Trust when weighted per 100 admissions (National Patient Safety Agency 2013).

In addition, in voluntary incident reporting, individuals' scoring of patient harm may vary. However, clear guidance was available on the electronic incident reporting system and also in supporting documents electronically available. Furthermore, the incident manager verified the harm score, and the Hospital Assurance Department also aims to review all incidents reports. The calculation of OBDs was based on midnight census which may underestimate the actual number of patients especially with rapid patient turnover, however, this is less relevant to MAIs as at every time medications are due to be administered there can only be one patient in the bed at that time.

2.5.7. Future work

In studies using incident report data, it is not possible to determine the denominator i.e. the number of prescriptions, or the number of administered doses in order to calculate the incident rate to the number of opportunities for incident. For most commonly involved drugs also, it has been suggested that the high number of administration incidents with some drugs or classes may be linked to their higher prescribing rate or dose frequency. For more reliable and valid comparison, identifying the incidence of

incidents associated with specific drugs or groups of medication using "the number of opportunities for incidents for this drug" may provide greater insight (Kiekkas et al. 2011). When electronic prescribing and medication administration are more widely available in the UK, facilitating capture of data on drugs prescribed and doses administered, future work could use number of prescriptions or doses administered as a denominator, to provide greater insight into the risk associated with specific drugs or classes (Kiekkas et al. 2011).

Dose omissions are reported frequently in the current study and many of the drugs reported in this study are considered time sensitive (National Patient Safety Agency 2010, Institute for Safe Medication Practices 2011). Hospitals are required to reduce medication omission and delays. This should be the subject of future research in order to improve patient safety. Finally, determining the main causes and contributing factors of all MAIs is essential for any future work or intervention to reduce these incidents.

2.6. Conclusion

Medication administration incidents represented around half the MIs reported in an acute teaching hospital, consistent with UK and USA voluntary reporting studies. The medicines involved were consistent with previous studies. Whether extent of harm or frequency of incident reporting is considered, omitted or delayed dose, and wrong dose, frequency, or infusion rate were the most common MAI types. These data identify the important role of registered nurses in the safe use of medicines. Paediatric locations reported many MAIs in total but critical care had the highest reporting rate per OBDs. Use of the total number of MAIs reported in each location appears simplistic, and weighting reported MAIs rates by beds occupancy may be a better method of prioritising efforts for improvement.

Chapter 3. An Exploratory Study to Investigate Nurses' and Midwives' Views of the Contributing Factors and Causes of Medication Administration Incidents in Hospitals

3.1. Introduction

3.1.1. Nurses and medication administration

Patient safety is a major part of nurses' clinical practice (Elliott and Liu 2010). Drug administration is an essential part of the nurse's role and correct administration of medication is one of their responsibilities. Up to one third of a nurse's time is spent on activities related to medications (Keers et al. 2013) and it has been suggested that administering medicines is the riskiest job a nurse undertakes (Anderson and Webster 2001). Furthermore, the nurse is the last person before a drug is administered that can ensure the medication is correctly prescribed and dispensed (Davey et al. 2008). Therefore, nurses play an essential role in patient safety in preventing harmful errors from affecting the patient (Rothschild et al. 2006). In the absence of effective safeguards to prevent medication administration errors (MAEs), nurses and patients can be at a high risk during the medication administration stage (Elliott and Liu 2010). Therefore, understanding the nature and causes of MAEs is essential to develop more efficient defensive barriers and strategies in order to prevent errors during the administering stage (Ozkan et al. 2011, Keers et al. 2013).

3.1.2. Problems of medication administration

Medication-related incidents were reported to be more frequent during the administration stage compared to other stages of the medication process. In the UK, the proportion of MAEs among all reported errors from all stages ranged from 46.5% to 58% (Ashcroft and Cooke 2006, Picone et al. 2008, Alrwisan et al. 2011, National Patient Safety Agency 2013). In addition, other observational studies on MAEs in healthcare settings have shown high rates of errors during administration. In the UK, observational studies have reported MAIs occurred in 3.5% to 38% of doses administered, if wrong timing incidents were included (Franklin et al. 2007, Kelly et al. 2011). Internationally, the incidence of MAEs varied between 2.6% to 60.5% of all doses administered by nurses (Ridge et al. 1995, McNally et al. 1997, Barker et al. 2002, Tissot et al. 2003, Van Gijssel-Wiersma et al. 2005, Reifsteck et al. 2006, Franklin et al. 2007, Maricle et al. 2007, Bertsche et al. 2008, Climent et al. 2008, Biron 2009, Chua et al. 2009, Jimenez Munioz et al. 2010, Poon et al. 2010, Gokhman et al. 2012, Rodriguez-Gonzalez et al. 2012). In an international systematic review of MAEs in inpatient settings, the observed median error rate was 19.6% of the total number of

administered doses, if wrong time errors were included. When timing errors were excluded from the total, the error rate was 8.0% (Keers et al. 2013).

A higher rate of error was observed during the preparation and administration of intravenous (IV) doses, especially with doses requiring multiple step preparations. The observed error rate in IV doses ranged from 7% (n=32/249) (Taxis and Barber 2003) to 31% (42/134) (Wirtz et al. 2003) during the IV preparation process and ranged from 8% (118/1391) (Anselmi et al. 2007) to 49% (53/109) during administration process (Wirtz et al. 2003). The overall rate of error in preparation and administration ranged from 25% (Bruce and Wong 2001) in a UK-based study to 69.7% in Australia and the UK (Cousins et al. 2005, Westbrook et al. 2011).

In paediatric patients, the worldwide incidence of MAEs found in observational studies ranged from 1.2% to 49% of all administered doses (Schneider et al. 1998, Prot et al. 2005, Conroy et al. 2007, Taylor et al. 2008, Raja Lope et al. 2009, Chua et al. 2010, Ozkan et al. 2011, Chedoe et al. 2012). In the UK, a study in five hospitals assessed the incidence and nature of MAEs in paediatric inpatients (Ghaleb et al. (2010). The investigators observed a total of 429 preparation and administration errors (19.1%) in 2249 opportunities for error over a period of twenty weeks. Drug preparation errors (20.7%) were the most common, followed by wrong administration rates of intravenous doses (19.8%), and wrong time (18.7%).

In terms of the most common types of these errors, in studies in which timing errors were reported, timing errors usually turned out to be the most common type of reported or observed errors. Omissions and wrong dosage errors were also among the three most common error types. In studies not including timing errors, the three most common errors were omission, wrong dosage, and unauthorized drug administration (Berdot et al. 2013, Keers et al. 2013, Kongkaew et al. 2013).

In errors associated with IV doses, the two most common types of IV preparation errors were use of the wrong solvent/diluent and preparation of the wrong dose. The most common types of errors associated with IV dose administrations included administering bolus doses faster than the recommended rate, wrong infusion rates, and incompatible

administrations (Taxis et al. 1999, Taxis and Barber 2003, Wirtz et al. 2003, Taxis and Barber 2004, McDowell et al. 2010, Westbrook et al. 2011).

3.1.3. Medication administration policy

The aim of medicine administration is to make sure that the correct medicine and formulation is administered in the correct dose, at the correct time, by the correct route, and to the correct patient (Gill et al. 2012, Nursing Midwifery Council 2012). In the UK, all NHS trusts are required to have a Medicines Policy which must include medication administration procedures, in line with the NMC code of conduct standards for medicines administration (Nursing Midwifery Council 2012). The national NMC is considered the regulator for nursing and midwifery in the UK and the study Trust follows the Council's guidance for the administration of medicines (Nursing Midwifery Council 2012, Trust Drug and Therapeutics Committee 2015).

3.1.3.1. Authority to administer medicines

Healthcare professionals who are involved in preparing and administering medicines in the study Trust (registered nurses/midwives, bank nursing and midwifery staff, and Agency nursing/midwifery staff) must have undertaken the essential training and have met Trust approved competencies for medicines. In addition, specific training is required for some specific groups of medicines (e.g. IV doses, handling/administration of cytotoxic medicines) (Table 3.1) (Nursing Midwifery Council 2012, Trust Drug and Therapeutics Committee 2015). In the US, the task of medication administration is performed by registered nurses (RNs) and Licensed Practical Nurses (LPNs) who are only authorised to administer oral medicines and pre-mixed IV antibiotics when they have demonstrated competency in this area (Table 3.1) (Boston Medical Center 2010).

Table 3.1. Authority to administer medicines in USA and UK (Boston Medical Centre 2010, Trust Drug and Therapeutics Committee 2015)

USA	UK
• Only RNs may administer IV push/bolus medications, either manually or via IV infusion pumps. • LPNs can administer pre-mixed IV antibiotics when they have demonstrated competency in this area. • Student nurses may administer medications under the direct supervision of a nursing instructor. • Senior nursing students affiliating for independent learning experiences may administer medications (with the exception of IV push medications) under the direct supervision of the RN preceptor. • Paramedic students may administer medications under the direct supervision of the RN preceptor in the Emergency Department only.	• Once registered with the NMC, nurses can administer medicines, ensuring their own competence and adherence to the 26 standards set out by the NMC • In the study trust, registered nurses/midwives and Bank staff are required to pass a written medicines management test before joining the Trust. In addition, at the time of this work nurses must have completed a Trust medicines management competency assessment document. • All conditions of the Medicines Policy are also applicable to bank nursing and midwifery staff who are considered Trust employees. • Student nurses/midwives are given the opportunity to practice the medicines administration under supervision of a registered nurse/midwife, who will be held accountable for the student's practice. Student staff cannot administer IV medication. • Patients and carers may administer medicines when appropriate. However, their ability for safe medicine administration must be assessed within the Trust before undertaking self/carer administration (with the responsibility on the nurse to ensure that the medicine has been taken as prescribed and also to continue assessing the patient's ability and competency for self-administering)

3.1.3.2. Standards for practice of administration of medicines

The Trust's standards and process for oral and IV medicines administration follows the national guidelines for the administration of medicines (Box 1.1) (Nursing Midwifery Council 2012, Trust Drug and Therapeutics Committee 2015). Medicines must only be given against clear, valid written directions or prescriptions by an authorised prescriber, and must include a completed allergy statement. Medicines may be administered to patients following a verbal direction in exceptional circumstances and after a confirmation and documentation of the prescription in the patient notes by two registered nurses or midwives.

Box 1.1: The Trust's standards and process for oral and IV medicine administrations (Trust Drug and Therapeutics Committee 2015)

Before administering medicines, nurses and midwives must:

- Ensure the patient's identity and allergy status.
- Know the therapeutic uses of the medicine and its dosage information, as well as precautions and side effects.
- Be aware of the patient's plan of care.
- Check the legibility of the prescription or the label of medicine dispensed and that is clearly written and unambiguous.
- Check the expiry date of the medicine being administered.
- Consider the correct drug, dosage, method, route, time of administration and patient's weight where appropriate.
- Checking the medicine has been stored appropriately e.g. in the refrigerator.
- Accurately and instantly document all medicine administered, or withheld or refused by the patient, reporting the reason for any withheld or not administered doses. Any administered medicine including 'as required', variable dose and once only doses must be documented in the prescription or the appropriate section of the in-patient drug chart. For non-regular doses, the dose administered, time and the date given may additionally need to be recorded.
- Independent double checking is required for the preparation and administration of controlled drugs, cytotoxic Chemotherapy, intrathecal medicines, complex calculation, and IV preparations.

3.1.4. Studies on the causes and contributing factors of medication administration errors

Many causes and contributing factors to MAEs have been reported in the literature. These related to work environment, medication administration task, patients, working team, individual nurses, and organisations.

3.1.4.1. Environmental factors

The majority of studies reported heavy workload and interruptions and distractions as an important contributory factors to errors (Gladstone 1995, Hand and Barber 2000, Tissot et al. 2003, Balas et al. 2004, Mayo and Duncan 2004, Deans 2005, Jones and Treiber 2010, Ozkan et al. 2011, Gill et al. 2012). Studies which used interviews or conversations (with or without observation) or surveys with open-ended questions were more able to give more detailed data about the sources and nature of these distractions which included ward rounds (Taxis and Barber 2003), and conversations with colleagues or patients (Jones and Treiber 2010, Reid-Searl et al. 2010). Some studies reported that interruptions were associated with increased workload (Taxis and Barber 2003) and/or poor supervision (Reid-Searl et al. 2010). Workload was also found to

combine with patient acuity, shortage of staff, inexperience or local working practice to lead to other errors (Balas et al. 2004, Nichols et al. 2008, Jones and Treiber 2010).

Insufficient staffing was identified by many research studies as a cause of MAEs (Hand and Barber 2000, Balas et al. 2004, Deans 2005, Jones and Treiber 2010, Treiber and Jones 2010). Balas et al. (2004) identified that inadequate staffing prohibited nurses from complying with procedures properly, giving medicines on time, and assessing new patients correctly. Skill mix was also reported by some studies: Hand and Barber (2000) stated that lack of trained and qualified nurses contributed to errors while others reported working with inexperience or new nurses may contribute to errors (Deans 2005, Tang et al. 2007).

Additional factors related to the physical work environment involved the busyness of the area (Taxis and Barber 2003, Balas et al. 2004, McBride-Henry and Foureur 2007, Jones and Treiber 2010, Kim et al. 2011, Gill et al. 2012), noise and lightening (Deans 2005, Gill et al. 2012), and a chaotic environment (Balas et al. 2004, Jones and Treiber 2010). Studies involving open-ended surveys offered more details and related factors to inadequate staffing level, heavy patient load and acuity and poor supervision (Jones and Treiber 2010). Problems with drug charts were also identified and involved absence or misplacement of drug charts especially with distracting and noisy environments (Hartley and Dhillon 1998, Chua et al. 2009, Reid-Searl et al. 2010).

3.1.4.2. Task factors

Many task related factors were identified by different studies. Inappropriate checking (involving both basic checks such as patient name, drug name, dose, route, and time and also preparations and administrations which require double checking) and inadequate compliance with administration protocols were frequently reported (Tang et al. 2007, Ulanimo et al. 2007, Chua et al. 2009, Dickinson et al. 2010, Jones and Treiber 2010, Reid-Searl et al. 2010, Gill et al. 2012). Although in most cases this faulty checking was considered personal neglect and constituted violation, nurses in one study mentioned that unclear responsibility of the second checker was a contributing factor to MAEs (Sanghera et al. 2007). Small number of studies discussed the causes and circumstances behind this practice and suggested that it may lie in the reliance between staff, workload, and nurses' familiarity with the drug or patient.

A recent study by Alper et al. (2012) to assess violations among nurses during medication administration found that violations were highest when checking patient ID, checking medication against the patient record, and documenting medication administration. The study found that being in an emergency situation and familiarity with the patient contributed to these violations. In addition, Jones and Treiber (2010) found that nurses' feeling of being newly registered was related to violations in performing some required safety checks as they felt that they were under pressure to complete the round within the time. Similar findings were reported by Gill et al. (2012) who examined the compliance of nurses with the medication administration and checking protocol using questionnaire and focus groups. Gill and colleagues found that inappropriate checking of patient identity and double checking were common and that the local culture, drug type, familiarity with drug or patient, and workload all affected the compliance with appropriate checking.

Quality of prescriptions was also mentioned as a cause of errors. Illegible or incomplete, unclear or unreadable prescriptions which lead to misreading the orders were found to contribute to MAEs (Hand and Barber 2000, Mayo and Duncan 2004, Deans 2005, Tang et al. 2007, Jones and Treiber 2010, Treiber and Jones 2010) although nurses in one study cited that they feel that it is their responsibility to be sure about the prescription before administering the drug if they were unsure about what had been prescribed (Hand and Barber 2000). In addition, errors of transcribing prescriptions by nurses were reported to contribute to MAE by two studies in countries where nurses are expected to transcribe the original orders written by physicians (Taxis and Barber 2004, Kim et al. 2011).

In terms of medicines supply and availability of medicines, two studies found that the delayed deliveries of medicines by pharmacy contributed to delay in administration (Kim et al. 2011, Ozkan et al. 2011) and two studies referred omissions and wrong timing errors to the non-availability of drug in the ward at the time of administration (Bruce and Wong 2001, Rodriguez-Gonzalez et al. 2012).

Some factors related to the local working culture (i.e. due to bad practice) were also reported as causes of MAEs. Administering medicines without a completed prescription and trusting other colleagues led to errors in four studies (Taxis and Barber 2003, Taxis

and Barber 2004, Sanghera et al. 2007, Reid-Searl et al. 2010). Some MAEs (e.g. omission and extra dose errors) were found to be caused by documentation errors during prescribing and administration (e.g. failure to document the administration) (Chua et al. 2009, Jones and Treiber 2010, Treiber and Jones 2010, Gill et al. 2012).

Few studies reported factors related to policies and protocols and involved failure to follow the standards and protocols of medication administration (Gladstone 1995, Balas et al. 2004, Gill et al. 2012) and insufficient or unclear protocols (Ozkan et al. 2011). However, in cases of not following protocols, it was not clear whether it was deliberate and therefore violation or not. Confusion with medications that look or sound alike as well as medications with similar packaging was also identified by some studies to be a contributor for errors (Deans 2005, Tang et al. 2007, Jones and Treiber 2010, Reid-Searl et al. 2010, Treiber and Jones 2010).

3.1.4.3. Team factors

Poor or lack of supervision of students and agency nurses was found to play a role in MAE causation (Taxis and Barber 2003, Jones and Treiber 2010, Reid-Searl et al. 2010, Treiber and Jones 2010). This affected medication administration in many ways involving pressuring junior nurses to prepare and give the drug more quickly, lack of assistance and support, and lack of clear instructions. Two studies linked that to the overconfidence in or from other staff when communicating instructions (Jones and Treiber 2010, Treiber and Jones 2010). In contrast, other studies showed that appropriate supervision and communication between staff has improved patient safety by preventing errors before they reach the patient (Balas et al. 2004, Reid-Searl et al. 2010). Poor verbal and written communication between nurses and with other teams is an issue reported by many studies although these papers did not provide much details about the nature of this communication (Balas et al. 2004, Deans 2005, Sanghera et al. 2007, Nichols et al. 2008, Jones and Treiber 2010).

3.1.4.4. Personal factors

Lack of experience, knowledge and/or training either with medications or being 'new' or an agency nurse was reported by the majority of studies as a factor contributing to errors and in some studies which used human errors theory this was directly linked to knowledge-based mistakes (Gladstone 1995, Taxis and Barber 2003, Sanghera et al.

2007, Tang et al. 2007, Chua et al. 2009, Jones and Treiber 2010, Treiber and Jones 2010, Ozkan et al. 2011). Inadequate knowledge was expanded back by one review to inadequate teaching of clinical pharmacology in universities (Brady et al. 2009). Limited nurses' knowledge about high-risk' medications such as cardiovascular and electrolytes was also identified to be associated with MAEs (Lu et al. 2013).

Errors due to calculation failures were also reported and were mainly associated with wrong dose preparation and administration. Although some studies did not determine whether these were due to inadequate calculation skills of nurses or not (Deans 2005, Chua et al. 2009), others revealed that poor calculation skills contribute to an increased risk of nurse error especially in areas where more complex calculations are required during medicines administration, such as paediatrics (Gladstone 1995, O'Shea 1999, Armitage and Knapman 2003, Dickinson et al. 2010).

Staff feeling of fatigue/tiredness or lack of sleep were reported by many studies as a contributor to medication error (Mayo and Duncan 2004, Deans 2005, Ulanimo et al. 2007, Nichols et al. 2008, Jones and Treiber 2010, Treiber and Jones 2010). More details were provided by three interview and open ended questionnaires studies (Tang et al. 2007, Jones and Treiber 2010, Reid-Searl et al. 2010) which linked fatigue to some specific shifts such as long shifts, and night shifts, and also to lack of breaks.

Poor physical and mental condition was reported as common contributor to MAEs although limited examples of these conditions were provided. Reported physical status involved physical discomfort (Tang et al. 2007) and being unwell (Gladstone 1995). Mental state of nurses during error occurrence was also reported; stress which was always due to increased workload was found to lead to errors (Gladstone 1995, Deans 2005, Nichols et al. 2008, Jones and Treiber 2010). Other less common individual factors such as lack of confidence/assertiveness was identified by Gladstone (1995).

3.1.4.5. Patient- related factors

A number of studies reported contributing factors for MAEs related to patient characteristics. Patient clinical condition (acuity) and/or unfamiliarity with the patient condition were reported by six studies (Balas et al. 2004, Tang et al. 2007, Nichols et al. 2008, Jones and Treiber 2010, Treiber and Jones 2010, Ozkan et al. 2011). Absent or

sleeping patients at the time of drug administration was also a common problem resulting in errors of omissions or delays which in two studies constituted a violation as nurses were aware of the omission (Hand and Barber 2000, Bruce and Wong 2001, Balas et al. 2004, Ozkan et al. 2011). Less common patient factors related to patient behaviours involved non-cooperation by the patient during drug administration and refusing to take the drug (Hand and Barber 2000, Taxis and Barber 2003). Finally, two studies reported that unfamiliarity with the patient condition contributed to errors (Tang et al. 2007, Nichols et al. 2008).

3.1.4.6. Organisational factors

Not many studies reported factors related to the organisations and high level decisions. Sanghera et al. (2007) considered lack of feedback on errors important factor to error repetition and limited learning from mistakes. Similarly, Deans (2005) and Reid-Searl et al. (2010) found that providing regular feedback about errors had a positive impact on nursing practice. Using open-ended responses, Jones and Treiber (2010) highlighted the importance of involving nurses in organisational strategies to minimise errors. Finally, one study linked the confusion with medications that look or sound alike to hospital management and pharmaceutical industry (Taxis and Barber 2003).

3.1.4.7. Causes for intravenous medication errors

Few research studies examined the causes of errors in preparation and administration of IV doses. Two studies (Taxis and Barber 2003, Taxis and Barber 2004) concerned mainly with causes of IV doses errors in UK and German hospitals respectively, while other studies considered this issue after describing error prevalence and type during preparation and administration of IV doses (Hartley and Dhillon 1998, Bruce and Wong 2001, Wirtz et al. 2003). All these studies used direct observation to investigate IV drug errors. Taxis and Barber (2003) and (2004) collected additional data from informal talks with observed nurses, then applied human error theory as a framework to analyse and classify incidents.

Many factors related to the task of preparation and administrations of IV doses were reported. Problems of intravenous access such as lack of or limited intravenous access were common, causing various error types including wrong route administration, compatibility errors (Wirtz et al. 2003), wrong timing, medication deterioration (Bruce

and Wong 2001), omission (Hartley and Dhillon 1998), and were not linked to a specific type of error in one study (Taxis and Barber 2003). Difficulties with using drug administration equipment such as syringe drivers and pumps contributed to incorrect administration rate (Hartley and Dhillon 1998, Taxis and Barber 2003, Taxis and Barber 2004). Problems associated with infusion pumps were also reported by a few non IV route studies and included un-calibrated pumps leading to incorrect administration (Chua et al. 2009), and different pumps properties leading to non-applicability of the pump to some drugs and therefore omissions (Ozkan et al. 2011). One UK study (Taxis and Barber 2003) reported complex or unclear design of technology such as unclear or complicated presentation of vials, and preparation procedures. Other less common factors found to contribute to MAEs in IV doses involved incomplete labelling, which led to deteriorated drug errors (Bruce and Wong 2001), calculation errors (Bruce and Wong 2001), documentation errors, non-availability of blood tests (Hartley and Dhillon 1998), and unclear prescriptions (Taxis and Barber 2003, Taxis and Barber 2004).

Lack of knowledge about preparation or administration of IV doses including how to use infusion equipment, wrong administration technique (e.g. co-administering incompatible infusions), and unclear and ambiguous procedures, guidelines and manufacturer leaflets were common causes of IV errors (Taxis and Barber 2003, Taxis and Barber 2004). Taxis and Barber (2004) reported that in Germany, nurses do not have adequate knowledge for safe preparing and administering IV medications and that nurses were not assessed appropriately for IV drug administrations. In their UK study, violations, which were mainly deliberate administering of doses faster than recommended, also caused by lack of knowledge as most nurses were not aware about the potential risk of such a practice (Taxis and Barber 2003).

In terms of working environment, skill mix and lack of qualified nurses, poor communication between nurses, and workload, which was combined with multitasking and interruption, were found to lead to errors in IV administration (Bruce and Wong 2001, Taxis and Barber 2003, Taxis and Barber 2004).

3.1.5. Comments on the methods used and limitations of studies

Numerous research methods were used to collect data on the causes of MAEs including qualitative and quantitative self-reported surveys and questionnaires, qualitative

interviews, focus groups, and direct observation (Osborne et al. 1999, Ulanimo et al. 2007, Cohen and Shastay 2008, Jones and Treiber 2010). Less commonly, staff used daily log books (Balas et al. 2004). Some studies used mixed methods, such as Tang et al. (2007) who used a focus group followed by semi-structured questionnaires and Gladstone (1995) who collected data using three different sources: medication error reports, questionnaires to nurses, and face-to-face interviews with nurses that had been involved in medication errors. Some research papers reported data matching Reason's classification of active failures to determine the primary cause attributing to MAEs (Taxis and Barber 2003, Taxis and Barber 2004, Ozkan et al. 2011). These studies primarily reported slips, lapses, mistakes and violations.

Although there were inconsistencies between studies in term of the methods used, the most common causes and contributing factors identified from the studies were similar. Nonetheless, studies differed in the level of details provided. For example, studies which relied on interviews or conversations (with or without observation), focus groups or self-reporting methods with free text responses were able to provide detailed information about the variety of MAE causes. In some cases, they linked the causal factors to specific MAEs (e.g., incorrect frequency) unlike those that relied on structured methods, such as short answer surveys/questionnaires (Tang et al. 2007, Jones and Treiber 2010) or those that used direct observation methods alone (Tissot et al. 2003); these provided a lower level of details.

The critical incident technique (CIT) (Flanagan 1954) was used as a method to investigate and analyse causes of adverse events. This qualitative and retrospective method requires collection of data about AEs from the people involved in these events by use of questionnaires, interviews, and, occasionally written statements. This CIT was considered a valid method to collect and analyse data on clinical incidents (Vincent 2003). However, the main limitation of this approach is that the collected information relies on participants' memories, which can be affected by hindsight bias (Flanagan 1954). Another limitation of this approach, which is a limitation of self-reporting methods in general, is that obtaining data from persons directly involved in incidents may be affected by the individuals' opinions and awareness more than their experiences of specific errors, which may not reveal the real causes behind errors (Keers et al. 2013). In contrast, the observational method used by Tissot et al. (2003) may be a more

reliable method to collect data about causes of MEs because it is divorced from the opinions of persons directly involved in the errors, assuming, however, that it is not affected by observer opinion as well (Keers et al. 2013). Moreover, with an observational approach, the observer can identify deviations from policy that the staff do not notice. However, a limitation of studies employing direct observation alone, such as that of Tissot et al. (2003), is that the observer may be unable to investigate the processes that underpinned a staff error.

Therefore, some studies have combined observational methods with interviews (Chua et al. 2009, Ozkan et al. 2011) or informal conversations with staff involved (Taxis and Barber 2003, Taxis and Barber 2004) to determine error causality. The main advantage of such methods is that collecting data using this method can bridge the gap between causes of errors that the observer would be unable to discover alone and those errors that would not be recognised by the person committing an error (Mays and Pope 1995, Keers et al. 2013). In addition, this approach can overcome discrepancies between actions that the participants state they have undertaken and those that they actually do in practice (Keers et al. 2013).

In studies that used surveys/questionnaires, although some included open-ended questions (e.g., Jones and Treiber 2010), others only used a prepared list of contributory factors from which participants chose (Deans 2005, Tang et al. 2007). Such pre-prepared lists can be considered a limitation because list of causes and contributing factors to MAEs presented to nurses might not have been comprehensive nor included all possible causes. Findings of studies conducted at only one site or one unit may not be generalisable to other settings (Fry and Dacey 2007, Sanghera et al. 2007, Ulanimo et al. 2007).

Finally, in some studies considering only the IV administration route (Hartley and Dhillon 1998, Bruce and Wong 2001, Wirtz et al. 2003), the main focus was predominantly on the prevalence and nature of administration errors. Therefore, these studies did not obtain any data from persons involved in the errors. This was considered a limitation even by the authors themselves as they could not identify some important personal causes.

In conclusion, many studies have investigated the causes of medication errors in general, with few focused on MAEs. Different methods were employed by these studies to collect data. Although these studies varied in their methods, study hospital drug distribution systems, settings, and the nature of errors investigated, factors like interruption and distraction, workload, length and type of shift, quality of prescriptions, and lack of nurse knowledge and training were found in almost all studies. Some contributing factors varied depending on the systems used in the hospitals and study settings.

A few studies, particularly from the UK, focused on the causes and contributing factors of MAEs and considered the perception and views of nurses using qualitative interviews to gain insight into nurses' ideas. Furthermore, no such work has been conducted on causes and factors that contribute to MAEs in the study trust, although several recent changes have been introduced into the study trust. Changes include changing the shift lengths to twelve hours and introducing automated dispensing cupboards to wards. In addition, the study Trust recently recruited many nurses, especially within critical care units, thus there are now a lot of junior and inexperienced nurses working in the trust. These changes in environment and staffing may have an impact on medication safety, particularly in medication administration.

3.2. Aim and objectives

3.2.1. Study aim

The aim of the study is to describe the perceptions of nurses and midwives regarding the contributing factors leading to medication administration incidents.

3.2.2. Study objectives

- To identify the causes and contributing factors leading to MAIs, from the nurses' and midwives' perspectives.
- To identify nurses' and midwives' views and opinions about why these causes and factors are present.

3.3. Methods

3.3.1. Study design

Since the 1990s, qualitative research approaches have gained an increased importance in health services and pharmacy practice research (Smith 1998), as well as in nursing research (Brookes 2007). Qualitative methods are considered appropriate for investigating new topics or topics about which little is known, as well as complex or sensitive topics. Such methods are used to provide insight and in-depth information on complex matters (Bowling 2009). Qualitative research methods are considered the methods of choice for the questions about "how?" and "why?'' phenomena occur. Data gathered from qualitative research is able to explore and understand the ways and patterns in which people think and behave. Unlike quantitative methods, which follow the researcher's viewpoint and are based on a standardised approach, qualitative methods are more flexible and receptive to respondents' viewpoints (Smith 1998).

The most frequent methods used in qualitative research include observations, individual interviews, focus groups, open-ended questionnaires, and document analysis (Al-Busaidi 2008, Bowling 2009). Individual interviews are most commonly used and found to be a functional way to investigate individuals' perceptions and understand how they make sense of their own world (Bowling 2009). Furthermore, qualitative interviews are the most commonly used qualitative approach in research of health services and pharmacy practice (Smith 1998). Interviews are also considered an interactive method which allow for rich data to be gathered through the interaction between the researcher and interviewee**.** The researcher is able to use prompts and probes to obtain detailed answers about the topic discussed (Ritchie and Lewis 2003). Although focus group is more time efficient as many people can be interviewed at the same time, this qualitative approach documents the views of public rather than individuals and some participants may do not interview well in group situations (Al-Busaidi 2008).

There are three types of interviews: structured, semi-structured and unstructured or in-depth interviews. The semi-structured interview is the more frequently used qualitative method in health care research, such interviews are based on a flexible topic guide and consists of open ended questions on the topic investigated, to explore participants'

experiences and thoughts and to elicit their own views (Al-Busaidi 2008). Semi structured interviews can be considered half-way between gaining information about the issues of interests to the researcher and providing the opportunities to the respondents to express their views (Smith 1998). Therefore, it was decided to carry out interview-based research using a semi-structured interviews approach to address the objectives of the current research. This method allowed understanding and gaining insight to nurses' and midwives' perceptions and views about causes and contributing factors of MAIs.

3.3.2. Study settings

The study was conducted at a large central London teaching NHS Foundation Trust. At the time of the research, the Trust was one of the largest NHS teaching trusts. It is comprised of an acute site including paediatrics, a specialist site approximately 2 miles away and other adult and children's community services in the local area. It has a total capacity of 1100 beds. The Trust provides a full range of hospital services for the local community and also provides tertiary referrals (specialist services) for many medical and surgery specialities including cancer, cardiothoracic, women's and children's services, kidney care and orthopaedics. The Trust has one of the largest critical care services in the UK.

During the study period, some departments had an electronic Prescribing and Medicines Administration system "ePMA" in place, however, in other areas, ePMA had not yet been implemented and paper drug charts were used for prescribing and recording medication administration. The medication distribution system is typical for the UK and includes ward stock, where each ward stores a limited range of commonly used medications. Less frequently used medications which are not ward stock are ordered for individual patients from the pharmacy. On the ward, medications are stored either in the ward medication stock room or in the patient's bed side locker. Registered nurses are responsible for preparing most medicines before administering them to patients. However, pharmacy prepares some high risk drugs such as chemotherapy which are available as "ready to use" from the pharmacy.

3.3.3. Development of data collection tools

3.3.3.1. Career questionnaire

A career questionnaire (Appendix 1) was developed to identify and select eligible participants according to the eligibility criteria and sampling strategy described below. Questions assessed participant eligibility to participate. This career questionnaire consisted of three sections: the first section requested information about the participant's current job including years of practice in the current trust, employment status, working shifts, current job title and grade, and area where the participant worked. The second section involved information about their experience as registered nurses or midwives, and the final section of the questionnaire involved the contact details of the participant.

3.3.3.2. Participant information leaflet

A participant information leaflet was developed to provide detailed information about the study to participants (Appendix 2). Information provided in this leaflet included the study background, aims, eligible participants for the study, the participant recruitment process, potential benefits from the research, any possible risks, participant's rights (see section 3.3.6.3 for details), anonymity and confidentiality of participation, plans for publication, and contact details of the research team in case the participant required any further information about the study.

3.3.3.3. Study invitation letter

The invitation letter (Appendix 3) was attached with the study invitation email and also provided information about the study including the aim, background, what participation involves, and what to do if they are willing to take part. The contact details of the research team members were provided in both the invitation email and letter in case participants required any further information.

3.3.3.4. Consent form

A consent form was developed to be read and signed by the participants before conducting the interview (Appendix 4). Receiving the signed form was essential before conducting the interview. The consent form consisted of questions requiring a yes or no answer about the participant's agreement to participate, recording the interview using audio tape, and anonymously using interview data in presentation of the research. At the

end of the form, contacts details of the research team were provided in case the participant required any further information about the study.

3.3.3.5. Interview schedule

The interview schedule (Appendix 5) used to guide the interview, was developed to collect key details about contributing factors and causes behind medication administration incidents based on the framework of factors influencing clinical practice developed by Vincent et al. (2000). This framework was developed for analysing risk and safety in clinical practice and classified error-producing conditions into task, environmental, team, patients, organisational, or individual factors that affect performance.

The schedule was divided into four main sections. In the first section, participants were asked to give brief background information about their daily practices in administering medicines and were asked to describe the steps they take when administering medicine. The second section focused on the perception of the participant of different causes and contributing factors to medication administration incidents, based on the classification of error-producing conditions by Vincent et al. (2000) and Dean et al. (2002), consisting of environmental, task, team, patients, organisational, and individual factors. The third section consisted of one general question about factors which specifically increase the risk of incidents during preparation and administration of IV doses and how, in practice, participants avoid these factors. Under each section, prompt questions were used to ask for more clarification and explanations if required. In addition, issues raised by the participant were discussed and participants asked for any clarification required. Interviews were audio recorded for a verbatim transcription and written notes were taken by the interviewer as well.

3.3.4. Research permissions

Initially, ethical approval from the Biomedical Sciences, Dentistry, Medicine and Natural & Mathematical Sciences (BDM) Research Ethics Subcommittee (RESC) at King's College London (KCL) was acquired for this study on 9th May 2013 **(**BDM/12/13-72**)**. Following the pilot interviews, a modification request form was submitted to approve the amendments to the career questionnaire and study poster. Approval was gained for the requested modifications on 19th December 2013. The

research was also approved by the Research and Development department at the study Trust on 6th September 2013 and allocated a Trust R&D registration number RJ113/N228.

3.3.5. Piloting of data collection tools

Both the career questionnaire and interview schedule were piloted by two nurses between August and October 2013. First, these two nurses were asked to complete the career questionnaire used to select eligible participants, and then they were interviewed. The pilot aimed to assess the clarity and validity of questions in the career questionnaire and interview schedule and to ensure that key details were collected clearly without any potential for confusion. This pilot resulted in the amendment of two questions in the career questionnaire in order to improve participants' understanding of the questions. The amended questions were question 2.1 about the length of participant's registration as a nurse or midwife which was changed from "*For how long have you been registered as nurse?*" to becom "*For how long have you been registered as nurse or midwife?*" and question 2.2 about the eligibility of the participant to administer IV medicines to patients which was changed from "*Are you eligible to administer parenteral (injectable) medicines to patients?*" to become "*Are you eligible to administer intravenous (IV) medicines to patients?*"

In the interview schedule, the layout of the schedule, as well as the order of some questions, were amended to enable better follow up by and interaction with the interviewer. The pilot interviews also allowed the interviewer to practice and develop his interviewing skills while asking questions and interacting with participants. The amended documents were then piloted by interviewing another two nurses to ensure their appropriateness for data collection.

3.3.6. Study participants

3.3.6.1. Inclusion and exclusion criteria

All registered nurses and midwives involved in drug administration in all study directorates were invited to participate. Nurses or midwives who were practicing in settings outside study directorates and any nurse who did not administer medication for

any reason were excluded. Nurses or midwives who did not respond to the reminder letter within seven days, according to recruitment process were also excluded.

3.3.6.2. Sampling

The anticipated sample size was twenty-five nurses or midwives selected to represent a range of Trust directorates, professional backgrounds and experience. The minimum sample sizes required to achieve saturation in interview based research is twelve interviews and therefore, it was assumed that the determined sample size would be appropriate to generate relevant codes and themes about the topic (Dean et al. 2002, Guest et al. 2013).

Nurses and midwives were selected based on their experience, grade, and directorate or department where they worked. Directorates included in this study were Children's Services, Acute Medicine, Surgery, Perioperative, Critical Care and Pain, Women's Services, Oncology and Haematology, Cardiovascular Services, and Abdominal Medicine and Surgery. In each directorate, nurses or midwives with different levels of experience (newly qualified nurses to 10 + years of practice) and different grade/seniority (from Band 5 to senior nurses or ward manager) were invited and selected to participate to reflect the diversity of nurses and midwives' backgrounds. Moreover, the number of nurses or midwives invited from each directorate was based on the number of registered nurses and midwives working in each directorate (Table 3.2).

Table 3.2. Study settings and participants (sample size=25)

Staff grade	Perioperative, Critical Care & Pain	Children's Services	Surgery	Medicine and Surgery	Women's Services	Acute Medicine	Cardiovascular service	Oncology & Clinical Haematology
Band 5	2	2	1	1	1	1	1	1
Band 6	2	1	1	1	1	1	1	1
Band 7	1	2	1		1	1		

3.3.6.3. Participant rights

Participation in interviews was entirely voluntary and participants were able to withdraw from the study at any point up to the date of the research report, which was specified as 9th January 2015, without giving any reason. During the interview, no sensitive, embarrassing or upsetting topics were raised or discussed. In addition, participants were free to refuse to answer any question they were asked during the interview. Therefore, it was unlikely that any participant would suffer any undue distress, harm or injury. Furthermore, the interviews were confidential and all identifiable information disclosed during the course of the research was anonymised by the researcher. The researcher explained to participants that information from the research would not be linked back to participants. Finally, the contact details of research team members were provided in all study documents and research communication (emails) in case participants had any question or needed any further information.

3.3.7. Participant identification and recruitment process

All Trust nurses and midwives were informed about the study and invited to participate at least seven days before the start of recruitment to increase awareness about the study and also to provide the opportunity to ask if they have any questions or wanted further information about the study. This was done using a poster (Appendix 6) displayed in prominent nurses' and midwives areas at all study wards (Figure 3.1). Copies of the career questionnaire (Appendix 1), and the participant's information letter (Appendix 2) were also provided with the poster. Moreover, information about the study was sent via group emails for nurses, matrons and ward managers, to all Trust nurses and midwives to inform them about the study and to invite them to participate. This invitation email provided brief information about the study involving the aim, approvals obtained, eligible participants, what the participation involve, and what to do if they were willing to take part. Furthermore, a copy of the invitation letter, career questionnaire, and participant information letter were attached to the email.

Staffs interested in participating were asked to complete and return the career questionnaire either by internal mail or by email to the researcher. Following receipt of the career questionnaires from nurses or midwives willing to participate (first stage data collection), twenty-five eligible participants, selected according to the sampling strategy, were invited for interview.

This staffs were sent an email with a personalised interview invitation letter for the interview, copies of the participant information leaflet and consent form. Two copies of the consent form were provided; one for return to the research team, and the other to be retained by the participant. Selected participants were given one week to consider the invitation letter and if required to contact the research team to discuss any aspect of the study. Non-responders were sent a reminder letter (Appendix 7) after seven days. Any participant selected who did not subsequently respond to the reminder letter within seven days was excluded from the study and an alternative eligible nurse selected from the career questionnaire respondents was contacted and invited to participate. When the acceptance for interview (consent form) had been received, participants were contacted to arrange the time and location for the interview (second stage data collection). Respondents not eligible to participate and those not selected for interviews received a letter from the research team to thank them for their willingness to participate.

3.3.8. Data collection and processing

3.3.8.1. Conducting the interview

Interviews with nurses or midwives were conducted between February and August 2014. All interviews took place in a quiet room on the ward where the participant worked or in the pharmacy department in the study trusts. At the beginning of each interview, the researcher provided general brief information about the study and the nature of the questions. The participant was asked to verbally confirm that they had read the information leaflet and that they had read and signed the consent form.

3.3.8.2. Data storage

To ensure confidentiality and data security of all study information, electronic data files were saved on a password protected and encrypted USB drive. All study data including career questionnaires, final interview transcripts, consent forms, and all USB drives which were used to store electronic files were stored in a locked filing cabinet. Audio-tape recordings were destroyed at the end of the study. Each participant was given a reference number which was used throughout the study and stored separately from their contact details. Only a member of the research team had access to this data.

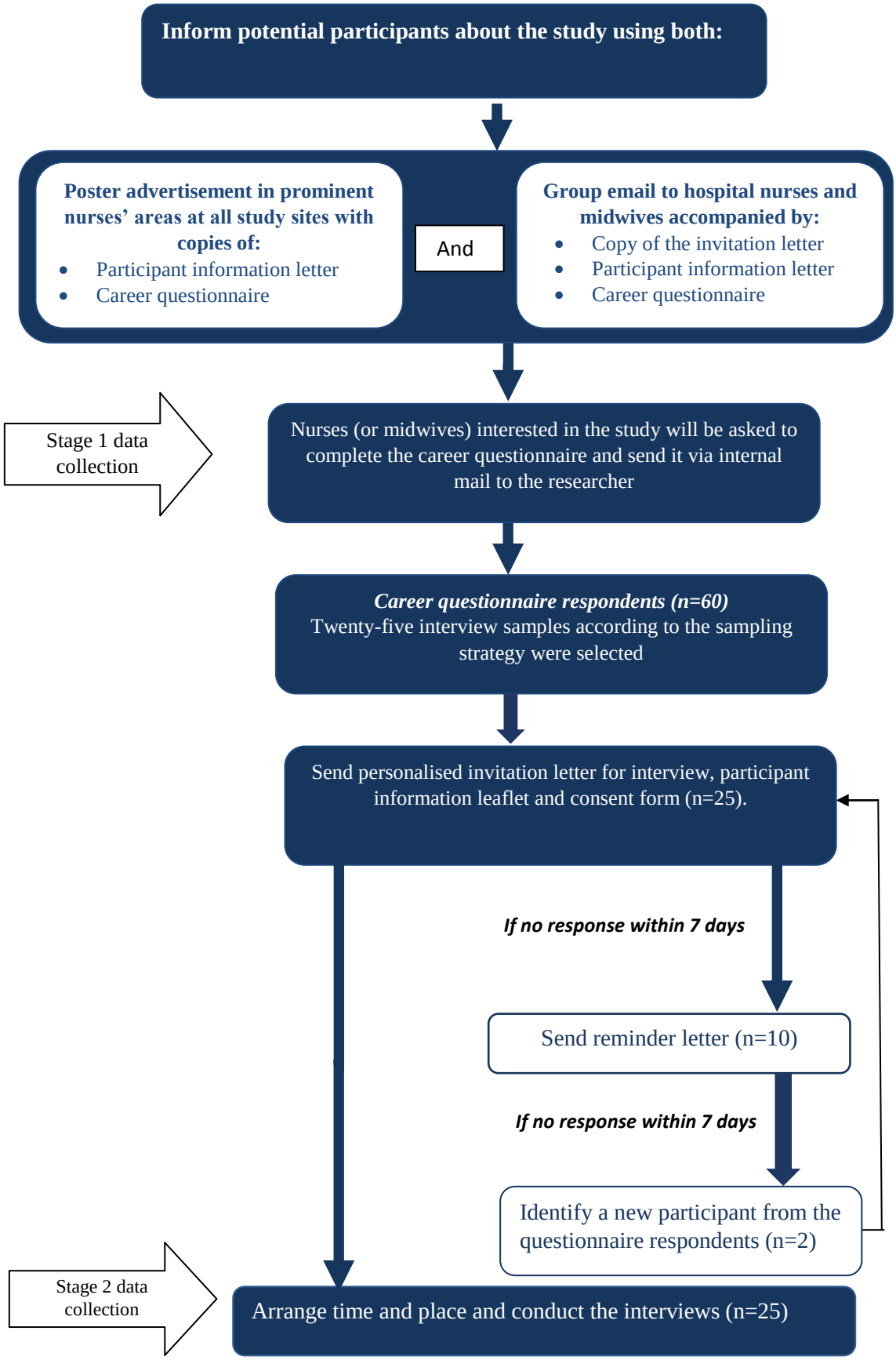

Figure 3.1. A flow diagram of participant recruitment and data collection process

3.3.8.3. Data analysis

All anonymised interviews were subjected to framework analysis method, which sits within a qualitative analysis method named "thematic analysis" (Gale et al. 2013, Vaismoradi et al. 2013). Thematic analysis is a qualitative descriptive approach for data analysis which is used frequently as analysis method for qualitative studies in nursing research (Vaismoradi et al. 2013). The use of such qualitative descriptive analysis is considered suitable for research which require a relatively low level of interpretation, in contrast to grounded theory where higher level of interpretive complexity is needed (Vaismoradi et al. 2013). It was described as "a method for identifying, analysing and reporting patterns (themes) within data" (Braun and Clarke 2006, p79). The Framework Method is commonly used to thematically analyse semi-structured interview transcripts (Gale et al. 2013). The following processes were followed to analyse the data as described by (Vaismoradi et al. 2013):

- **Transcribing the data:**

The anonymised audio recordings were transcribed verbatim and cross checked against the recording and the researcher's written notes. All transcripts were then read and cross checked against the recordings by one of the supervisors (CW) who made any required changes to the written transcripts to assure that all recordings were accurately transcribed.

- **Familiarisation with data:**

Familiarisation with the data was achieved by listening and re-listening to the audio recording and reading the transcripts and any written notes, and generating initial ideas. Re-listening to the interviews and re-reading the transcripts several times were performed if required.

- **Generating initial codes**

Initially, transcripts of the first few interviews were coded into different codes and each section of the text was assigned to the relevant code. These codes were refined by analysing the rest of the interviews. To avoid ignoring any data, we added an 'other' code under each theme for any data that did not fit with any code.

- **Searching for themes and developing a working analytical framework**

Generated codes were gathered together into themes and a coding framework was developed which summarised emerging themes. This coding framework was further refined by analysing the rest of the interviews.

- **Reviewing themes**

Generated themes were checked to assess whether they were appropriate in relation to the coded texts and also the whole dataset. The developed framework or thematic map was refined if necessary by either merging or gathering codes.

- **Defining and naming themes**

At this stage of analysis, the specifics of each theme were refined and each theme was defined and named.

- **Producing the report**

Reporting the results of all previous stages was the final stage of data analysis. This stage was considered as "the final opportunity of data analysis in thematic analysis" (Vaismoradi et al. 2013p402) where the extracted data from the interviews was interpreted and related back to the research objectives and literature.

The computer software NVIVO (version 10) was used during analysis. The pilot interviews were not included in the analysis. Before producing the report, the analysis was validated by a supervisor (CW) in order to check the main researcher's coding and verify the outcomes and any disagreements were discussed and resolved.

3.4. Results

3.4.1. Study participants

Following the study advertisement and the invitation email to all Trust nurses, a total of 60 selection questionnaires were returned from nine directorates; of which 32 were collected from the ward by the researcher, 18 questionnaires were received via Trust internal mail, two were sent by email, and eight were given to the ward pharmacist, who in turn delivered them to the research team. Five of the received questionnaires were

excluded, either because of insufficient contact details provided (n=4), or because the respondent was not eligible to participate (n=1), leaving 55 completed questionnaires from eligible participants. Non-eligible questionnaire was received from Genetics, Rheumatology, Infection, Dermatology, and Allergy (GRIDA) directorate, which was not included in the study.

Initially, a total of 25 interview invitations were sent to 25 selected questionnaire respondents, according to the sampling strategy (Table 3.2). There was a response to fifteen invitations, and then interview times and venues were agreed. Non-respondents were then sent a reminder letter seven days after the first invitation letter. Two nurses responded to the reminder letter and eight nurses did not. Therefore eight alternative participants were selected from the questionnaire respondents and invited to interview until 25 interviews were completed. Interviews were conducted either in the small seminar room in the pharmacy department (n=8) or in the ward where the participant worked either in a nurses' offices or in an unoccupied room on the ward (n=17). The average time of the interview was 41min 17sec (range 67min 07sec – 27min 29sec).

Of interviewed nurses, seventeen were from the acute site while eight nurses were from the specialist site. Nurses were from Children's Services (n=5), Acute Medicine (n=3), Surgery (n=3), Perioperative, Critical Care and Pain (n=5), Women's Services (n=3), Oncology and Haematology (n=2), Cardiovascular Services (n=2), and Abdominal Medicine and Surgery (n=2). Nurses from grade 5 (n=10), 6 (n=6), and grade 7 (n=9) were interviewed. The length of time since registration ranged from less than two years to more than 30 years. All participants were eligible to administer intravenous doses. Their experience in IV administration ranged from one month to more than 30 years. Most nurses were employed full time (n=23/25), while some were working part time (n=1/25) or were temporary (i.e. agency, or bank) (n=1/25). Details of participants' characteristics can be found in Table 3.3.

3.4.2. Interview results

Analysis yielded seven main themes and 58 codes or sub-codes from the interviews topic guide about causes and factors contributing to MAIs. The main themes identified were environmental factors, task factors, patient related factors, team factors, management factors, personal or individual factors, and factors associated with IV. The

environmental factors theme included interruption and distraction, workload, staffing levels and staff skills mix, shift patterns, and physical environment. The theme of task factors consisted of 8 codes involving factors such as inappropriate checking or double checking, non-availability of test results or procedures, design and clarity of the task, and also the individual drugs related factors (i.e. medicines which increase the risk of incidents). The third theme was patient factors, which involved 5 codes about patient related factors and also involved the groups of patients who were believed to be at higher risk of errors. The fourth theme consisted of 4 codes and 4 sub-codes and focused on team factors such as support, communication, and supervision. The fifth theme, which was comprised of 5 codes about management or organisational factors, related to higher levels such as training and education provided to staff. The sixth theme was the staff individual factors which may contribute to MAIs such as the fatigue and tiredness of nurses, and lack of knowledge or skills. This theme involved 8 codes. The seventh theme consisted of 4 codes and 4 sub-codes and in this theme, nurses described factors contributing to errors associated with IV doses. Table 3.4 presents the identified codes and created themes.

3.4.3. Environmental factors

Different factors related to the working environment revealed by interviewees were mainly distraction and interruption during medication administration, workload, understaffing and skill mix, shift patterns and the noise of the ward.

3.4.3.1. Interruption and distraction

The majority of nurses from all directorates mentioned that interruptions and distractions was an important factor affecting their attention levels during the preparation and administration of medicines and in consequence, could lead to errors.

> *"I think the interruptions as well, is a big problem. You can be on a drug round and be interrupted 10 times, and then you can lose track.***" (N19 Surgery)**

> *"I think the only thing I would think of is concentration because if there is noise everywhere and everybody coming to distract you, definitely there will be an error especially if the person is a newly qualified nurse."* **(N24 Abdominal Medicine and Surgery**)

Table 3.3. Demographics of the participants (N=25)

Participants' characters	N (%)
Site	
Acute	17 (68%)
Specialist	8 (32%)
Directorate	
Children's Services	5 (20%)
Perioperative, Critical Care & Pain	5 (20%)
Acute Medicine	3 (12%)
Surgery	3 (12%)
Women's Services	3 (12%)
Abdominal Medicine and Surgery	2 (8%)
Cardiovascular Services	2 (8%)
Oncology and Haematology	2 (8%)
Eligible to administer IVS?	
Yes	25 (100%)
No	0
Years of working at the study trust	
2 years or less	9 (36%)
>2 – 5 years	3 (12%)
>5 – 10 years	8 (32%)
>10 – 15 years	2 (8%)
>15 – 20 years	1 (4%)
>20 years	2 (8%)
Employment status	
Full time	23 (92%)
Part time	1 (4%)
Temporary (agency or bank)	1 (4%)
Type of shifts worked	
Day shift	5 (20%)
Evening shift	0
Night shift	1 (4%)
Multiple shift	19 (75%)
Job title	
Ward manager	4 (16%)
Deputy ward manager	3 (12%)
Ward sister	2 (8%)
Practice development nurse	1 (4%)
Staff nurse	14 (56%)
Midwife	1 (4%)
Band	
5	10 (40%)
6	6 (24%)
7	9 (36%)
Years since registration as nurse	
Less than two years	7 (28%)
2 – 5 years	4 (16%)
>5 – 10 years	4 (16%)
>10 – 15 years	1 (4%)
More than 15 years	9 (36%)
Gender	
Male	5 (20%)
Female	20 (80%)

Table 3.4. The identified codes and created themes

Codes	Themes
Area layout or geography Business of the area Cluttered medicines area Interruption and distraction Non-availability and access to essential equipment and supplies Physical environment Shift patterns and duration of the shift Staffing level and skill mix Unfamiliarity with the area Workload	Environmental factors
Design of drug chart Inappropriate checking Medicines with high risk of incidents Non-availability of test results or procedures Timing of medicines Quality of prescribing Relying on doctors and pharmacists Other task factors	Task factors
Communication barriers and language Lack of patients' medication history Patients' non compliance Clinical condition and acuity Patients' personality and cooperation	Patient factors
Lack of nurses support Communication between nurses Communication with doctors The supervision	Team factors
Clarity and applicability of policies and guidelines Inadequate training from the management Lack of communication with the staff Lack of feedback about errors Lack of updates to nurses	Organisational factors
Fatigue Lack of knowledge, skills and experience of nurses Lack or over confidence Old ways of doing things or habits-short cuts Physical health (being tired, hungry, unwell) Poor calculations skills Family issues Unfamiliarity with the task	Personal factors
Confusion with different administration routes Lack of training and experience on IV medications Complexity of the preparation of IVs Problems with cannulation and setting the infusion rate	Factors to do with IVs

Although the interviews revealed that interruptions can occur at any time and in all areas, some nurses explained that in busy areas and during busy times such as early in the morning, interruptions and distractions are more likely to happen.

> *"You're more likely to be interrupted in the morning around 8 o'clock because that's … the busiest time the doctors are coming in for ward around and things. So you're more likely to be interrupted there."* **(N13 Cardiovascular Services)**

Different sources of distractions were reported. However, the main source of interruption as mentioned by most nurses was patients, who may ask questions in the middle of their own drug rounds or request help.

> *"I mean the patients often will not realize how important what you're doing is and might, uh, ask for help or, uhm, ask for ..., sometimes the patient you're administering drugs to, you know might ask something in the middle of their own drug rounds, so that's also something."* **(N11 Cardiovascular Service)**

Other sources of distraction stated by nurses involved other nurses asking questions or requesting double checking, other health care professionals, primarily doctors during ward rounds, telephone calls, and patients' relatives or parents, especially in paediatric wards.

> *"Interruption from patient, interruption from your colleague because you might be doing medication and somebody will come up and say, "Oh, I'm looking for this tablet and I cannot find it. Can you help me? Sometimes it's the doctors. You're doing medication, they will come and maybe they ... they ... they ... they come and tell you, "Are you the one looking after that patient?"* **(N24 Abdominal Medicine and Surgery)**

> *"Uhm…so other nurses asking me questions, for example. Patients uhm either asking you questions or being slightly disruptive, can't think of a better word, you know, the…wiggling around the bed…putting themselves at risk, uhm so you have to stop halfway through; uhm if you have to take a phone call halfway through, if the doctors come and speak to you halfway*

> *through. Uhm…that what I was seeing…that was my distractions."* **(N17 Perioperative, Critical Care & Pain)**

The continuous interruptive nature of the intensive care units was also mentioned by some nurses working in this environment.

> *"The continuous distraction of the monitor and the patient's movements, deterioration, themselves. Uhm, phones going off, ward rounds arriving, other people asking questions and the nature of critical care work being that second by second there are changes occurring around you"* **(N20 Women's Services)**

3.4.3.2. Workload

The terms "rush", "busy", "stress", and "pressure" were all used by nurses to describe their workload. Most of the nurses commented that high workload was an important contributor to MAIs. Many nurses mentioned that the heavy workload lead them to do medication tasks in a rush and in consequence, cause them to make errors easily.

> *"The work load and pressure, you're looking at the time, you know that medication you have to give in certain time ... and you want to finish on that period of time. You're in rush. You can easily make mistake or errors. That can be one of the reasons."* **(N18 Surgery)**

> *"We had situations where you had two nurses giving the drugs for the entire unit, which was completely unmanageable with the amount of drugs have been given, and then more likely to making error because of the vast quantities that they've given."* **(N26 Perioperative, Critical Care & Pain)**

Excessive workload was linked to short staffing by a number of nurses, although one nurse related this to the patient's acuity rather than staffing levels.

> *"It's quite busy ward. It's very fast paced so I think if you're short staffed and you're rushing perhaps uhm, you don't read something properly, uhm, or you misread a time and you give it too you quickly when you shouldn't have given*

> *it, uhm, I think that's probably the biggest thing is people rushing."* **(N20 Women's Services)**

> *"The obvious one, really, is when it's extremely busy. Uhm, and sometimes ... I mean, you can be fully staffed on the ward, and officially you've got enough staff, but it's really, well, heavy, we would say because you've got patients who need lots of attention, patients who're sick and should be transferred, and you could be struggling even when you're fully staffed."* **(N11 Cardiovascular Service)**

Workload was often combined with challenging time management, particularly in busy times during the day (e.g. in the morning and between 6 and 8 in the evening as well, as at the end of shifts). Increased workload, multitasking of nurses (i.e. tasks assigned for nurses besides drug administration), and compressed time for drug administration; were reported as making it difficult sometimes to give all drugs on time, thus causing timing issues. In addition, with time pressure caused by excessive workload, nurses explained they were more likely to change their usual practice and take shortcuts to save time.

> *"if you've got a busy workload, if you've got maybe four or five patients to look after, you're trying to do the medications for those four or five patients, your conscious of the time, you know that you've got to try and get these medications done within the ... especially if they're intravenous medications and things like that. It's about, you know, the time constraints, whether you have got enough time and you're trying to think one job ahead the whole time, that's when errors happen"* **(D2 Children's Services)**

> *"Your time pressure is massive. You really struggle with time management and the medications are a big part of time management, so there's a lot of pressure, uhm, to rush through things."* **(N11 Cardiovascular Service)**

> *"If somebody has a lot of tasks that is multiple tasks to carry out at a particular point in time, it's about ... it will affect medication errors."* **(D22 Abdominal Medicine and Surgery)**

3.4.3.3. Shift patterns

Large number of nurses suggested that shift patterns were a major contributing factor to MAIs. Different shift patterns were indicated by nurses to be more error prone, mainly night shifts and long shifts (12.5 hour shifts), although a few nurses also reported the day shift, as well as irregular shifts was an issue.

Many nurses from different directorates indicated that long shifts in particular were associated with exhaustion and tiredness, especially at the end of such shifts, which might affect their vigilance and concentration when they administered medicine. A number of nurses also linked exhaustion and tiredness associated with long shifts to a lack of or inadequate breaks being taken.

> *"But I think in terms of medication you probably are tired by the evening and you … you … you might be more likely to make mistakes because you've been on … been on shift for 10 hours and you're tired and you're hungry and thirsty. So yeah … I mean yeah possibly more likely."* **(N25 Surgery)**

> *"Uhm…so we…we always work long shifts. We do 12 and half-hour shifts, mixture of days and nights. Uhm you know as the shift goes on, you get more tired towards the end of the shift and you're less…your concentration is diminished, uhm especially if you've had a very busy shift and you've not necessarily had your breaks as well as you could have done so you haven't rehydrated and eaten and things. Uhm I'd say that the later you get to in a 12 and half-hour shift, the more likely you would be to make a mistake while giving medicine because you… like I say, your focus is diminished."* **(N17 Perioperative, Critical Care & Pain)**

Many issues specific to night shifts were identified. The main issue was about the responsibility of night shift nurses to administer the 6 o' clock intravenous doses before handover to the morning staff. At this point, night nurses explained they were at the end of their 12 hours shift and were more likely to be tired.

> *"When we looked at the shift patterns, uhm, and I'm looking again back into once upon a time we used to dispense medication 6 o' clock in the morning and it used to be our night staff that would do it. So at the end of the night shift, we thought, yeah, it could be a rise and increase of medication errors as a result of people were tired at six in the morning."* **(N13 Cardiovascular Service)**

> *"Night shifts for me are a nightmare. I'm not good on night shifts. Some people are really good. Some people aren't. I'm sort of aware of that, so at 6:00 am when you do your big round of morning drugs because that's when most of them are administered, I have to concentrate really, really, really, really hard because I'm so tired by that point. I would…I'm frightened of making a mistake at that point because I know that I'm tired, so the risks are higher* " **(D17 Perioperative, Critical Care & Pain)**

Some nurses also explained that during the night and weekends, they did not receive the same support from other healthcare teams as they receive during the day shift (i.e. from 9am to 5pm).

> *"I think night shifts can be a bit less supportive because obviously you've got one pharmacist covering the whole hospital. So it's … it's a bit more challenging on night shift"* **(N23 Children's Services)**

> *"skill mix, generally speaking, during the week, uh, sort of on a Monday to Friday basis, we've got, uhm, clinical support nurses who come around and work with people. And there's a lot more staff on the unit so you can get people to watch your patient while you can go out and get stuff. On night shifts and on weekends, it's a bit trickier, and they tend to be less well staffed."* **(N26 Perioperative, Critical Care & Pain)**

In terms of the factors associated with the day shift, a few nurses thought that the day shift was associated with an increased workload as many tasks were done during the day shift compared to other shifts.

> *"I always find the medication rounds take longer in the morning, uhm, because there's things that they have once daily that they have in the morning. Uhm, so you're more likely I think to be rushing your drugs round in the morning than you are any other time, personally."* **(N20 Women's Services)**

3.4.3.4. Staffing

Staffing level was raised by many nurses from all directorates as an influential factor leading to errors. Staffing issues included inadequate number of staff, and thus increased workload, and skill mix in staff present on each shift.

> *"The only one I can look at is staffing ratio. If the staffing ratio is not right, it affects medication administration because the moment staffing ratio is bad; staff is bound to work under pressure. I was there working, it's terrible effect; goes down and it affects both quality of care and also judgments and then rushed decisions and then you'll see people making mistakes.'* **(N22 Abdominal Medicine and Surgery)**

The interviewees explained that issue of the skill mix was mainly due to newly qualified nurses, agency, and bank nurses who worked on a temporary basis and most of them were either unqualified to administer medicines or needed to be supervised and supported by a senior nurse. The nurses cited that on many occasions they have to take over the responsibility for patients, as well as their patients, resulting in a higher workload for them. In addition, some senior nurses identified that this can delay the medication if junior nurses cannot find someone to check with them.

> *"I think to start off with it is quite difficult on the team and such because uhm sometimes getting double the medication round because your colleague is too junior to do it by themselves. So there's a lot of pressure on the senior nurses to do that or you're having to double check everything with the junior nurses. So I think that phase is quite a difficult phase."* **(N7 Acute Medicine)**

> *"Certainly, when I was on xxxxx Ward, most shifts would have a bank or agency nurse on, at least one. They'd sometimes be on the bay on their own, although they'd generally be with another qualified member of staff. So...there's then I did pressure with my qualified member of staff to have to do more medications than just their own patient. Uhm If the bank or agency nurse or newly qualified nurse, who can't check at that point, can't find someone to check with them, then it can delay the medication. They might not get it on time uhm and then making it difficult for... to be able to catch up later on."* **(N1 Children's Services)**

Less common factors related to the work environment mentioned by nurses included the non-availability of essential equipment and supplies required for medication administration. These were mainly medicines not being stocked in the wards which needed to be requested from the pharmacy. They suggested this became more of an issue outside pharmacy working hours and during the weekend.

> "*Another ... Another factor of supplies is even the medication itself because every ward, for instance our own ward here we have got ward stock, which is on the list. Now, if a medication that is not covered on the ward stock, is not there on the ward…yeah and it is outside even during the working ... during the working hours, it takes a longer time for it to come from the pharmacy back to the ward from the time of ordering. It becomes worse out of hours when pharmacy for instance here is closed and then you have to source medication from St. Thomas's"* **(N22 Abdominal Medicine and Surgery)**

Other factors indicated by a few nurses included the layout and geography of the ward and related to the size or location of the drug room within the ward, as well as the small bed spaces, particularly in intensive care units. The physical environments of the ward, for example the ward temperature (especially during the summer), light, and the noise of the ward, and the familiarity of nurses with the working area were also reported.

3.4.4. Task factors

Several task related factors were thought by the interviewees to contribute to errors. These mainly involved failures in the checking processes and non-availability of test results required for some medicines. Less common factors involved the design of the drug chart, poor prescribing quality, and medication timing including those doses prescribed at busy times or those doses which are prescribed outside common times.

3.4.4.1. Inappropriate checking

Inappropriate checking was stated by most of the nurses interviewed as common practice and an important contributing factor for incidents. One of the things nurses they explained were easily missed was checking for allergies. Picking up the wrong chart and failure to check information the doctors 'had updated on the drug chart is also identified as common.

> *"I strongly feel if you don't adhere to…. checking the process that is in place, then you're going to cause … then you're going to have an error."* **(N23 Children's Services)**

> *"That's one of the major factors. Yeah. Checking process this year, one of the things that is very much responsible for medication errors"* **(N22 Abdominal Medicine and Surgery)**

> *"Allergies is easily forgotten because unless it has been flagged up to them as something significant, it seems to be not unusual to forget to go back to the beginning of the chart and check that"* **(N21 Perioperative, Critical Care & Pain)**

Different causes were revealed by the nurses to explain why they do not go through all the checking processes. A common cause was performing the medication task under pressure due to the heavy workload. Complacency among senior nurses and their reliance on their knowledge, experience and skills was also identified by the nurses as another common reason. Complacency was also identified by the nurses in cases when they looked after patients for a long period of time.

> *"I think a lot of the senior nurses kind of get into the, maybe there's a bit of complacency that, that things are all right and they are doing okay and they are not having any problems. Uhm, so they don't take as much care with what they are doing, or they are operating faster and they having to, you know, they…they know they got the knowledge and skills to kind of move real quick and do things a bit faster and maybe it encourages you to kind of cut corners and find work around if, you know, if the system doesn't work, you'll find a way around it"* **(N26 Perioperative, Critical Care & Pain)**

> *"Sometimes if a child been on a medicine for a long time people get a bit more complacent in checking that the right dose is being administered"* **(N15 Children's Services)**

A senior nurse stated that a lack of knowledge of newly qualified nurses had been noticed in both the checking processes and what should be checked.

> *"The checking process is either that the staff is in a hurry, to administer the medication then they rush the checking or sometimes some do not know what they are looking for. Some do not know what they're looking for and especially when the person is sometimes newly qualified and then the person starts medication very early doesn't know what he's looking for then that's could also affect medication administration."* **(N22 Abdominal Medicine and Surgery)**

Reliance on technology was also considered to make some nurses lazy regarding necessary checks of medication. Electronic drug cabinets was suggested an example of this as when nurses dispense their medicines using it, they assume that the correct drug was always dispensed and that the drug was within the expiry date.

> *"When you go into (the electronic) dispensing system, the expiry drugs shouldn't happen because the machine's supposed to, uhm.... automatically alert that it's going to expire. However, this is probably, well it is relying on humans to tell when you put them in about expiry dates and things. So, you, we wouldn't expect to take drugs out there which were expired, uh, and*

> *sometimes when you don't expect it, uhm, people do not check."* **(N13 Cardiovascular Service)**

In contract, some nurses believed that reliance on doctors and pharmacists could also contribute to checking failures. It was explained that some nurses might think that once the dose was prescribed by the doctor and dispensed by the pharmacist, then they could just give the medicine without checking whether the correct drug and dose was prescribed and dispensed.

> *"Sometimes people just think that…you know the consultant wrote this they must be right even though it's actually outside of the normal range."* **(N15 Children's Services)**

In doses which require double checking, mainly IVs and controlled drugs, the nurses often mentioned that appropriate independent double checking did not take place. The interviews identified that the nurses do not independently double check each step of the preparation and administration process. Common practice described by the interviewees was that the nurse prepared the drug and took it just before administration to the patient to another nurse (the second checker) and then the second person just signs but does not check it appropriately. Even if they check the preparation process together, the second nurse usually does not walk with the first nurse and watch him/her giving the drug to the patient. These were the most common practices for double checking as identified by the nurses.

> *"It's because uh for example I am busy and you would say, "Oh can you check with me. I'm just be putting it in front of you. I've mixed it." It is basically does this other nurse have the time to stand there with me while I'm preparing it to actually check if I'm doing it correctly because that is supposed to be the principle of double checking. You are there the whole way until you go to the patient itself and give it to them with both of you, but do we have that luxury? No. What you're going to do is you're going to prepare it, mix it up. You have your ampoules of the water. You have the medication ampoule there or vial. You have your syringes and then you have your drug chart and you're going to go to the nurse and say, "Can you*

> *check this with me?" and that's the double check which is actually not the principle of double checking."* **(N8 Acute Medicine)**

> *"Yes. So definitely the double signature thing. You know, you check everything yourself. You sign it and then take it to someone else. They check everything and they sign it but a lot of times you take it to them and they just sign it. They don't check it."* **(N12 Acute Medicine)**

> *"And one of the other problems with this system of checking is what you find that happens is that they'll check it for you, and we're quite good at thoroughly checking everything on the drug chart... and expiry dates and doses and all that kind of stuff. Uhm they will very rarely watch you walk over to the patient and give it to them. So, you know, you could take it to someone else, give to the wrong patient. And then they'd signed it, that you checked. And I have to say that's the normal practice"* **(N11 Cardiovascular Services)**

Short staffing, workload, and time pressure were common issues identified as barriers for double checking. Nurses explained it was sometimes found it difficult to find another nurse to undertake the double check, especially in the busy working environment. Other reasons for such practices were related by the interviewees to the local working culture and the relationship between nurses and overconfidence between nurses, especially when a junior nurse checks for a senior nurse. Some interviewees identified that junior nurses might felt embarrassing to challenge other senior nurses. One nurse described the problem as a cultural aspect as it has become acceptable not to apply the principles of double checking.

> *"People don't want to question the other person. You know like they just accept that what the person said is ...I think it's a bit like the double checking you know, they just go along with whatever the person saying because they don't like to upset or because they don't want to challenge somebody or they think that person knows more than they do. Of those sort of things."* **(N2 Children's Services)**

A senior nurse explained the national policy for double checking was unclear as the responsibilities of the second checker were not specified.

> *"Another factor is now, uh, staffing as part... as team, you were talking of team. When staffing is poor, medications that require double checking you always have problem with that. You always have problem with that because you will not always get a second person to double check with you and that affects ... affects the, you know, medication administration"* **(N22 Abdominal Medicine and Surgery)**

3.4.4.2. Non availability of test results

Non availability of test results required for some drugs was stated by some nurses as a cause for delay in some directorates. Misreading and misinterpreting the results e.g. reading the result of the previous day or looking in the wrong patient's file was also reported by a few nurses. In contrast, some nurses thought that this was not an issue for administration errors. Causes for delays in receiving some blood levels were identified as not taking the blood samples at the right time, delays in sending the blood samples to the central lab, and central lab delay problems.

> *"We've had a lot of incidents with, uhm, drug results availability, things like that. Uhm, INRs [International Normalised Ratio] for heparin, uhm, and titrating doses, uhm, medication ... so like ... things like gentamicin and vancomycin levels, uhm, being delayed in labs or not being sent by the nightshift when they do their bloods"* **(N26 Perioperative, Critical Care & Pain)**

3.4.4.3. Medicines which increase the risk of administration incidents

When nurses were asked about the medicines which may increase the risk of administration incidents, different drugs were identified by nurses. However, heparin followed by insulin administered as a sliding scale and doses that required blood levels before they could be administered were mentioned most often. The interviewees explained that the problem with heparin was that there were several protocols for its administration which sometimes caused confusion.

> *"When you're administering … Uhm, heparin is a massive one on ICU, uh, that is administered in different ways to different patients. So, the ability to understand the context that you're using it in for that patient is quite significant. So, there are different policies for it protocols for it."* **(N21 Perioperative, Critical Care & Pain)**

Preparing small doses and those doses which required complex calculations, particularly those working in paediatric wards, were also stated by some nurses as being associated with higher risk of error.

> *"We have very small patients here, so sometimes the medication doesn't come in something that is easily usable for a paediatric patient. So if you have to dilute something before you can use it, if you have to give very small volumes, then I think they're all things that help to contribute to drug errors."* **(N2 Children's Services)**

Additional uncommon task factors identified by interviewees involved the design of the drug chart, and poor prescribing quality. These factors might lead to missing some doses or misreading the prescription details and therefore leading to wrong frequency or wrong dosage errors. Timing of medicines was another factor and included either those doses which are due at busy times (e.g. 8:00 o'clock in the morning) when handover take place and therefore became prone to administration delay due to the business of the nurse at these times, or those doses which are prescribed outside common times e.g. 8pm. Doses prescribed outside common times were likely to be omitted because nurses automatically go to the drug charts at the times printed in prescription charts which are 8am, 12pm, 6pm and 10pm.

> *"I think only thing that comes to mind is the time of day. Uhm. Not talking about shifts and such. But uhm a lot of our medication missed-doses happen at 2pm. And that's because the ward becomes very busy with visitors. It's the middle of the day, and, it's, because our prescription charts state printed 8am, 12pm, 6pm and 10pm. The nurses automatically go to the drug charts at those time."* **(E1 Oncology and Haematology)**

3.4.5. Patient related factors

3.4.5.1. Patients' acuity and clinical condition

Several patient-specific factors were identified by the interviewees as possible causes of MAIs. The complexity of the clinical condition (acuity) of patients was the most common factor mentioned. Patients on multiple drugs, as well as confused, unconscious patients were also thought to be at higher risk of medication incidents.

Patients on multiple drugs were thought by the interviewees to place more stress on nurses and put them under excessive pressure, even if staffing level was adequate. Another problem identified by a few of interviewees was drugs charts, which can be messy due to the high number of prescribed medicines and sometimes mislead the nurse.

> *"Sometimes we'll say that it's to do with the 'heaviness' of the patient so if you're … if you have patients that are on a lot of medications and they're quite unwell and you have 5 patients to see, you're rushing because you know it's taking you ages to do one… lot of medication for one patient and you still have however many else to do. So you're rushing because your patients are 'heavier' not just because there's not enough staff"* **(N20 Women's Services)**

Additionally, the interviewees explained that confused and unconscious patients were usually unresponsive and therefore communication with such patients was difficult. This was thought to affect the ability of nurses to carry out some of the required checks such as patient's name and date of birth.

> *"Great of risk of incidents during preparation … I think all of our patients are at risk … by definition of being critically unwell. Uhm, a large majority of them are either sedated or in some way either unconscious or not … Even if they're not unconscious, they may be delirious or confused. So, in terms of being able to utilize that patient in the checking process and asking them questions about their previous allergies, their name; you don't have that facility, so you have to rely on your documentation and your name bands"* **(N21 Perioperative, Critical Care & Pain)**

> *"Some other times we have patients who are admitted who have dementia. ... who cannot even discuss their medication history with you. We also use trend of this and we make mistakes sometime."* (**N22 Abdominal Medicine and Surgery)**

In contrast, a few interviewees suggested that nurses would be more conscious and alert if they were looking after very sick patients and therefore those patients could be at lower risk of errors.

> *"So if a patient's not very well, I think nurses are a bit more .... hyper-alert, and in that sense, I think you're probably less likely to make an error, because you're very... you know, you're worried about this person, and you're questioning everything ... uhm, what should they have and what are they not having that they should be, and you know ..."* **(N11 Cardiovascular Service)**

3.4.5.2. Communication and language barriers

Language was mentioned as a barrier to communicating with patients by some nurses, causing difficulties in obtaining an accurate medication history for some patients, noncompliance by other patients sometimes when patients did not understand what nurses tried to explain to them about their medications. However, some of the interviewees thought that language did not contribute directly to drug errors, especially if an accurate drug history had been obtained.

> *"Yeah, it ...a lot. Uhm, language is an issue. I mean, we have plenty patients all the time who don't speak English very well, and some that have a minimum level of English.... which can be worse, sometimes because people assume they've understood when they haven't, and they say, "Yes," when they ... You know, they're embarrassed to, to say"* **(N11 Cardiovascular Service)**

> *"Obviously patients ... if there's a language barrier and English isn't thier first language its sometimes difficult if you're asking questions about when was the last time you took this or how, you know, generally just getting a*

> *history and how long they've been on these tablets and things its difficult"* **(N25 Surgery)**

Other communication barriers with patients identified by interviewees involved those patients who did not like to declare their own medications to the nurses, and pediatric patients who were sometimes too young to communicate with the nurse and provide accurate information about their drug history**.**

> *"Sometimes there is language problems or sometimes there are communication ... either because the child is too small to communicate, they don't have the communication skills, or there's a language difficulty in.... But The errors that seem to happen there is when they tell you the medication is, say they've already been on medication when they come in to the hospital, and then it's usually a transcribing problem. So they say that they have five milligrams or five mL you know three times a day, whatever and actually it's not five mL, it's five milligrams* **(N2 Children's Services).**

3.4.5.3. Other patient related factors

Other factors related to the patients were reported by some interviewees. These were lack of patient's medication history, patients' personality, for example agitated or chatty patients who interrupt nurses during tasks, and noncompliance of patients with their medications. Patients' noncompliance was either because the patient refused to take the medication or forgot to take it. In addition, patients being absent from the ward was mentioned as cause for many omissions and delays to administration of medication.

> *"They may be off the area at the time of the drug, and then the nurse doesn't get back to, when they come back because the 12 o'clock round is gone, they haven't been there for it, and sometimes they've forgotten it's not until the dinner 6 o'clock when they realise actually we should've given it at 1 o'clock when he came back and we've forgotten it"* **(N13 Cardiovascular Service)**

> *"If a child has been transferred over from another hospital sometimes uhm or from a ward, trying to work out, uhm because especially other hospitals have different uhm paperwork and things, you're trying to work out when they last*

had their medicines, uhm so sometimes that can be a contributing factor. " **(N15 Children's Services)**

3.4.6. Team factors

Team factors affecting the risk of administration errors were also discussed and most involved communication within the nursing team and with other teams, supervision, and less commonly inadequate support.

3.4.6.1. Lack of communication or miscommunication between nurses

An absence of communication or poor communication between nurses was stated by the interviewees as a contributing factor to administration incidents. Causes mainly included the absence of documentation on the drug chart to indicate that the dose was given or justification for not giving the medication, or lack of documentation of the actual time the drug was administered. Inadequate handover was also identified as another cause for miscommunication between nurses.

> *"I think sometimes if somebody is giving something and hasn't signed for it and then you come on the next shift uhm, and you think has this been given or hasn't it uhm, that for sure, definitely."* **(N20 Women's Services)**

> *"Yeah and the instruction is not read out or is not handed over to the next shift. There is a miscommunication in that. There is something missing in the communication and we go ahead and give the medication."* **(N24 Abdominal Medicine and Surgery)**

3.4.6.2. Lack of communication or miscommunication with doctors

A lack of communication or miscommunication with doctors was identified by the interviewees to occur in different ways. The most common cause as stated the interviewees was miscommunication that occurred within the drug chart and patient's notes when doctors prescribed something without informing the nurse, or when they gave verbal instructions without writing these down. This was identified as common practice by many interviewees. Another less common cause identified was the inability by a nurse to find the prescribing doctor when needed, poor hand writing and misplacing the drug chart by prescribing doctors or other nurses.

> *"If the doctor or you know pain team or whoever don't communicate with us and they … they sometimes write things in the notes but they don't verbalise it, if we're busy we … we can't always check back in the notes. So its som- again some things might be missed."* **(N25 Surgery)**

> *"One more thing is communication between the doctors and the nurses itself. Because when a doctor says that I need to give, prescribed some stat medications they don't say that…they don't tell us that. They go around, see the patient. They prescribe stat medications. They think that we as nurses will be there to know that they actually prescribed that. It's only until later when they actually go for the next drug round that they actually see that they have prescribed stat medications."* **(N8 Acute Medicine)**

3.4.6.3. Supervision

Inadequate supervision by senior nurses was reported by some interviewees, especially after completing the medicines management assessment test, and also in wards where inadequate senior nurses were available. In contrast, other interviewees considered that they did receive the supervision that they needed from senior nurses and also from practice developing nurses.

> *"I think we're in the birth centre, you know…you are very much left to do your own work. So, potentially, if you would …if you would You are very much left dealing with it and it's up to you to ask for help and support and clarification if you feel you need it"* **(N9 Women's Services)**

> *"We get that a lot especially, uhm, if you're a junior role with your newly qualified then you work with uhm people for period of time, uhm, and there's always at least two senior member staffs on the ward espe… on the day shift anyways is to oversee junior member staff and to help other team members so I'd say we're quite supported and supervised. Yeah."* **(N10 Children's Services)**

3.4.7. Personal factors

Personal factors were mentioned by the interviewees as being influential in administration errors. Factors identified included nurse's fatigue, a lack of knowledge, skills and experience of nurses, external issues or stress at home, and nurse' lack of confidence or over confidence when prepare or administer medicines to patients which may lead to non-adherence to all checking process.

3.4.7.1. Fatigue

The majority of interviewees explained that fatigue and tiredness were important contributing factors, leading to lose of concentration and then MAIs. Most of the interviewees also linked fatigue to night shifts, especially when fatigue is associated with inadequate sleep. The interviewees also identified that they become more fatigued at the end of long shifts. Many nurses also associated fatigue with hunger.

> *"Maybe just the tiredness. So I'm like going back to maybe been to having four days and if you're tired that could influence you making a drug error, uhm, yeah."* **(N10 Children's Services)**

> *"Likewise for night shifts, if you've not had any sleep you get to the end of the night shift, excuse me you going to be a little bit more slack with the checking process and with what needs to be done, when and what you doing as well, so definitely has a factor."* **(N1 Children's Services)**

> *"I think fatigue is a big issue probably in most nursing settings and, you know, night shift's the obvious time to suggest as an issue."* **(N21 Perioperative, Critical Care & Pain)**

3.4.7.2. Lack of knowledge, skills, and experience of nurses

Limited knowledge and experience about medications among particularly junior and bank agencies nurses was well recognised by the interviewees as a contributing factor for MAIs. Few of the interviewee extended lack of knowledge back to inadequate teaching of pharmacology in the universities. However, many interviewees also linked that to the inadequate training and assessment provided by the Trust for nurses especially when they join the Trust (i.e. competency test).

> *"We've got a quite high bank agencies, which is another, uhm, issue, and the bank staff usually are our staff are usually the work on the…permanently anyway so they get caught with the programs with the agency staff for completely separate. And I don't think we've got a specific sort of training program in place for them before they can come and work for the trust, they just turn up, do a shift and then disappear. And you know, it could just be one shift and then you'd never see them again."* **(N26 Perioperative, Critical Care & Pain)**

> *"I think the newly-qualified nurses, those ... that, that's quite a vulnerable ... if that's the right terminology ... They're a quite vulnerable group of nurses in terms of making medication errors. Because your training's a bit lacking"* **(N11 Cardiovascular Service)**

3.4.7.3. Lack or over confidence of nurses

The interviewees revealed that both complacency and lack of confidence might influence the occurrence of errors because complacent and over confident nurses were considered not to take much care when they perform medication tasks which may lead to errors. Lack of confidence among junior nurses was also reported as potential contributor to errors when they felt embarrassed or scared to ask or seek advice.

> *"I think a lot of the senior nurses kind of get into the, maybe there's a bit of complacency that, that things are all right and they are doing okay and they are not having any problems. Uhm, so they don't take as much care with what they are doing."* **(N26 Perioperative, Critical Care & Pain)**

> *"I think sometimes people get to a point where they're too embarrassed to come and ask and they don't know where to look for. So I guess that could cause error."* **(N17 Perioperative, Critical Care & Pain)**

3.4.7.4. Physical health

Physical health, tiredness or insufficient sleep, hungry, and sickness were reported by interviewees as contributory factors to errors especially when associated with inadequate breaks during shifts.

> *"You know being tired, hungry, missed your break. They're all factors that make you less able to concentrate at particular times but..."* **(N2 Children's Services)**

3.4.7.5. Other personal factors

Other personal factors mentioned by the interviewees in connection with administration errors included bad habits during performing medication preparation and administration tasks, non-adherence to the preparation and administration process, poor calculation skills, unfamiliarity with the task, unfamiliarity with the ward the nurses work in, and external issues or stress at home which may affect the nurses' concentration.

> *"You could argue that some of the junior staff are more thorough than some of the senior staff. Some of the senior staff, I think have slipped to bad habits, or perhaps were never taught in a structured methodical way in the first place, so they never adhered to what we would expect now."* **(N21 Perioperative, Critical Care & Pain)**

> *"If you're not familiar with that medication or it's something that, you know, is alien to the area that you normally work in, you know, sometimes you get patients that are...that have different conditions that get transferred to your ward and they have medications that you're not familiar with. I think they are factors."* **(N2 Children's Services)**

3.4.8. Management factors

The two main organisational factors identified by the interviewees involved inadequate training and education provided to the nurses, and lack of feedback to nurses themselves about medication errors.

Some interviewees considered that the education and also practical training provided by the Trust was inadequate including the training that the nurses undertake for the medicines management assessment test and also the continuous training once this has been completed. Nurses stated that apart from the medicines management assessment and calculation test which was taken when they joined the trust, nurses do not receive any sort of further training on medicines.

> *"I think it's just about training so it's … people do their medication course when they qualify but then there's no update. So nurses that maybe go off in maternity they come back, they forget things. There isn't generally any other training that you do and you obviously do your calculation test at the beginning when you first qualify and you don't do anything after that. So sometimes if you're out of practice or you know you work in a clinical area where you're not administering much medication then you move jobs that's where the mistakes happen."* **(N25 Surgery)**

> *"To be honest it's not really continuous because after you do your book you … you do … you do the medications and I know that in other hospitals you know they watch you do it and then you have to be signed off, uhm, you have be signed off while they watch you do it whereas on here it's not like that you go through the papers and then that's it. They don't watch you, uhm, do it. They just taught you and then that's it so, and then after that you do it yourself. You don't really …That definitely can, uhm, yeah contribute to drug error."* **(N10 Children's Services)**

Another organisational factor identified by the interviewees was the lack of feedback provided to nurses about medication errors. A number of the interviewees felt that there was lack of feedback on reported errors and because of this they did not learn from previous errors. However, lack of feedback factor looks ward base factor as some interviewees from some wards (e.g. Abdominal, and surgery) mentioned that they regularly received such feedback either in the weekly meeting or during handover. Senior nurses interviewed from these directorates also explained that they always try to deliver information about reported errors to their staff on a regular base. Most of the nurses interviewed considered feedback important and felt that more feedback on errors would be helpful

> *"We don't hear much on this ward, but uh, in other wards I've worked on in St. Thomas' I know they have uh regular target meetings, and I've attended some of these where, uhm, you know the heads of nursing will receive uhm, able to receive you know graphs and things that show them exactly the*

> *incidences and near misses that happened. And I think they're really useful"* **(N14 Perioperative, Critical Care & Pain)**

> *"We do get emails if there's been drug errors like things get highlighted to try and obviously stop something similar happening again. So I think they're quite good about bringing things to your attention. Uhm, yeah"* **(N20 Women's Services)**

Another organisational factor, reported less often by the interviews involved lack of updates about changes in medicines policies or products, the clarity and applicability of some policies and guidelines related to medication administration, and also lack of direct communication with people in the management as one of the senior nurses stated:

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> *"If the management in the organization needs to be approachable and open to the staff's suggestions and you know the staff's concerns. So if they are not listening and they are not open towards the staff, that can increase the risk"* (**N9 Women's Services)**

3.4.9. Factors associated with intravenouse medications

In addition to inadequate training provided by the Trust on IVs including the competency test nurses need to do that was mentioned before, two main factors associated with IVs doses were identified by the interviewees. One was the complexity of the IV preparation. The interviews identified that nurses struggle more with doses which required calculations such as paediatric doses, and/or doses which required further dilution. Interviewees from the intensive care units also reported that the confusion with different routes of administration might also lead to errors.

> *"The fact that the large majority of our medications are intravenous, so you've got central lines, Venflons [peripheral IV catheter], and in fact, that fact that you've got Venflons [peripheral IV catheter] and central lines is, it is a potential cause of problems because there are different routes of administration for different concentrations of potent drugs."* **(N21 Perioperative, Critical Care & Pain)**

> ***"****I think it's the preparation of… because you sort of prepare an IV in a certain amount of fluids or over a certain amount of time uhm… which isn't the same with oral and NGs because you just give them and they swallow them. Uhm, so, I'd say yeah it's the preparation, making sure it's the right solution and it ends up at the right concentration. That would be the ones for IV."* **(N17 Perioperative, Critical Care & Pain)**

> *Some doses are slightly more complicated uhm in what you have to…uhm how much you have to dilute it to, so and what you have to dilute it in and, uhm so that can…that can cause error"* **(N15 Children's Services)**

Another factor also discussed during the interviews was the lack of sufficient knowledge and training on how to prepare and administer IVs. The interviewees explained they had only basic information to help them safely mix and administer intravenous medications. Some of the interviewees considered that their intravenous drug administration skills were not appropriately assessed when they allowed preparing and administering IVs.

> *"I mean I suppose the IV course you have doesn't really do much with the practical side of it which could be a factor as well"* **(N15 Children's Services)**

3.5. Discussion

Twenty-five nurses and midwives from one large Trust participated in this qualitative interview-based study to describe the perceptions of nurses and midwives regarding the contributing factors leading to MAIs in hospitals. The nurses interviewed in this study were responsible for preparing and administering medication to patients and were selected to represent all Trust directorates at all seniority levels. Although previous studies have been conducted on the causes of medication errors, most of these studies did not investigate the causes of errors as the main aim, or investigated the causes of documented/reported or observed errors, or used self-reported/questionnaires which provided limited details about the topic.

The interviews identified a number of recurrent factors reported as contributing to incidents. The collected data were divided into seven main themes and factors related to the environment, task, patient, team, individual nurses, and management, all of which were identified as contributing factors to MAIs. In addition, some factors associated with IV doses were also identified. These factors were shown as areas to be addressed.

3.5.1. Work environment factors

The primary problems mentioned by the interviewees in relation to the work environment were heavy workload, interruption and distraction, staffing levels and staff skill mix, shift patterns, and physical environment, these have also been also identified by other studies.

3.5.1.1. Interruption and distraction

Interruption and distraction, which were reported by the majority of interviewees, have been previously reported in many studies as issues which affect the focus of nurses and as contributors to MEs (Pape 2001, Pape et al. 2005, Tang et al. 2007, Brady et al. 2009). Mayo and Duncan (2004) surveyed American registered nurses (n=983) to investigate their perceptions of MEs, and nurses believed that distractions were one of the top three causes of medication errors.

Although many studies reported interruption and distraction as main factors for MAEs, limited details about the rate, characteristics, and sources of interruptions as well as the relationship between interruptions and error in practice were provided (Raban and Westbrook 2014). In a review of twenty-three studies of the rate and characteristics of interruption in nurses' work environment and their potential contribution to MAEs, Biron et al. (2009) identified interruption rates estimated at 6.7 work interruptions per hour during a shift. The review also showed that nurses themselves were the most common source of interruptions, though some interruptions resulted from system failures such as missing medication. However, nurses in the current study identified that patients were a primary source, in addition to other sources reported, such as other nurses and other health care professionals.

Most previous studies which reported the contribution of interruption and distraction to errors were either qualitative studies or based on secondary analysis of incident reports,

which may constitute a limitation of underreporting. Furthermore, the interruption measures and frequencies were absent in most of the studies. However, a recent controlled study using direct observation was performed to determine the impact of interruption and distraction on MAEs in hospitals. Westbrook et al. (2010) used a sample of 98 Australian nurses preparing and administering 4,271 medications and showed a significant association between the rate and severity of MAEs and interruptions to nurses during MA. The study revealed that interruptions were present in 53% of administrations and that each interruption was associated with a 12.7% increase in errors. The rate of error increased from 25.3% in administrations with no interruptions to 38.9% in administrations with 3 interruptions. The severity of errors also increased with increased number of interruptions. Using the same method and a sample of 39 participants, Scott-Cawiezell et al. (2007) collected data on both work interruptions and rate of MAEs and identified a significant positive relationship between interruptions and MAE rate when wrong time errors were excluded (p = 0.01). Interestingly, when wrong time errors were included, the relationship was also significant but was reversed.

Although several interventions have been employed by different studies to minimise interruptions during the preparation and administration of medications and their effect on MAE rate, Raban and Westbrook (2014) assessed the effectiveness of these interventions on the rates of interruption and medication errors and concluded there was limited evidence to support their effectiveness on the rate of MAEs.

In order to limit the effect of interruptions, their characteristics must be understood; therefore, more descriptive studies on interruption during preparation and administration of medicines is required to better determine avoidable interruptions. In addition, examining how nurses manage interruptions in practice is another strategy requiring further investigation (Biron et al. 2009). Thus, further evidence on interruption management strategies used by nurses to minimise interruptions is required, in addition to controlled randomised or cluster randomised research to better assess the effectiveness of any interventions (Raban and Westbrook 2014).

3.5.1.2. Increased workload

Increased workload was also identified by most of interviewees in the current study as an important contributor to MAIs, particularly during the day shifts and at the end of night shifts. This is consistent with several studies on causes and contributing factors of MAIs which considered workload as one of the most common predictors of MAIs (Gladstone 1995, Tang et al. 2007, Cohen and Shastay 2008, Jones and Treiber 2010, Gill et al. 2012). Like other studies, our findings also showed that increased workload was mostly caused by inadequate staffing which, both in turn are related to organisational decisions regarding recruitment, although some interviewees linked this to the patient's acuity and others to the number of patients' medications rather than inadequate staffing.

Tissot et al. (2003) defined nurses' workload as "the number of patients per nurse" (Tissot et al. 2003 p69). The ratio of nurse to patient was commonly used as a measure for workload to investigate the relationship between nurses' workload and patients' outcomes (Aiken et al. 2002). However, this measure has some limitations, and workload was found to be multivariable and can be affected by several factors including the nurse/patient ratio, acuity of the patients, skill mix of the nurses, and shift pattern (Montgomery 2007). Other organisational factors may affect the workload such as cost-cutting strategies by having fewer staff (Jones and Treiber 2010), which led Reason to suggest that workload should be resolved at the organisational level. Taxis and Barber (2003) also found that increased workload combined with interruptions and distractions led to error in a study of causes of IV administration errors (Taxis and Barber 2003).

Interviewees revealed that workload-related errors included omissions and timing errors, which were reported to occur primarily during busy times. This may result from the multitasking nature of the nurse's job and working under pressure to administer medicines and perform other tasks besides drug administration at the same time. Multitasking during drug preparation and administration is a time-saving activity commonly used by nurses to manage workload (Brady et al. 2009). Results from other studies showed that workload also contributed to other types of errors. Ozkan et al. (2011) identified in their observational study that heavy workload contributed to all types of MAEs, particularly errors of wrong timing, while Tang et al. (2007) found that because of time pressure caused by workload, nurses were likely to make calculation

errors. In addition, studies which provided information about the origin of violations during medication administration suggested that situational violations by nurses may have been caused by high workload of nurses (Keers et al. 2013). A main form of these violations was nurse non-compliance with medication administration standards. Tang et al. (2007) indicated that the fact of time pressure and increased workload of nurses led them to modify the standard protocols of drug administration. In another recent study, nurses' compliance with standards of medication administration practice was found to be affected by increased nurse workload or patient acuity (Gill et al. 2012). Gill and colleagues found that workload, in addition to other factors, influenced nurses' compliance with the medication administration protocols as well as their compliance with the processes of checking and double-checking of medications (Gill et al. 2012). This is consistent with the current study, where nurses reported that the causes of inappropriate checking or non-compliance with the checking process, specifically with double checking, was mainly due to increased workload.

3.5.1.3. Staffing level and skill mix

The results of our study indicated that a majority of nurses believed that inadequate staffing and skill mix contributing to errors. Newly qualified, agency and bank nurses increased the workload of other nurses, as those nurses were either unqualified to administer medicines particularly IV or unfamiliar with the area and therefore needed to be closely supervised. These findings are consistent with other studies which reported short staffing and skill mix as a cause of MAIs, and similar to what was mentioned by the interviewees in the current study, staffing level and workload were collapsed into one factor by many other studies.

There is widespread evidence regarding the impact of nurses' staffing level and skill mix on patient safety outcomes in general, with few studies reporting data about medication errors (McGillis Hall et al. 2004, Ball 2010). The publication of the Royal College of Nursing (RCN) entitled "Guidance on safe nurse staffing levels in the UK" discussed different evidence which showed an association between inadequate nursing staffing and patient safety in hospitals. This report concluded that increased levels of registered nurse staffing were associated with lower rates of mortality and other adverse patient events. Over one year, the NPSA reported more than 30,000 patient safety incidents in England and Wales caused by staffing issues due to lack of experienced or

trained staff, and about 20% of these incidents were associated with harm (National Patient Safety Agency 2009).

Staffing level of nurses also has an impact on the rate of MAIs, as decreased nursing staff means increased in number of administrations per nurse and therefore increase in the possibility of making errors (O'Shea 1999). Poor staffing was found to promote errors by producing a busy environment, preventing nurses from administering medicines on time or conducting procedures correctly, and diminishing attention to detail (Balas et al. 2004, Tang et al. 2007). Furthermore, when short staffing was combined with increased patient acuity and heavy workload, it could lead to increased levels of stress and fatigue among nurses, further increasing risks to patients (Balas et al. 2004). Studies which examined the impact of nursing staff levels on the rate of MIs concluded that the rate of MAEs was decreased by increasing the number and experience of nurses. In a research undertaken to evaluate the impact of different nurse staffing models on patient outcomes, including medication errors, McGillis Hall et al. (2004) concluded that a lower proportion of employed professional nurses was associated with higher rate of medication errors occurring in the study units. This is consistent with Beyea et al. (2003) data which found that more than 30% of 206 medication errors were due to increased workloads and inexperienced staff. Using more reliable methods, Tissot et al. (2003) used direct observation to collect data on risk factors of MAEs and found that the risk of making an error was 2.44 times higher in nurses caring for more than 5.2 patients when compared to nurses with fewer than 5.2 patients.

Skill mix (e.g. the ratio of experienced nurses to inexperienced within nursing staff) has previously been found to affect safety of medication administration. Frith et al. (2012) examined the relationship between nursing skill mix and medication errors in 11 hospitals. The study showed a significant relationship between the proportion of registered nurses in the team and the occurrence of medication errors, as the proportion of ME decreased when the proportion of registered nurses increased and when the proportion of licensed practical nurses decreased.

In the UK, Ball and Pike (2009) surveyed nine thousand nurses and identified that more than 55% of surveyed nurses reported an increased workload when they provide care.

Those who felt that they were too busy were working in an environment with an average of 9.3 patients per nurse, compared those who reported that their workload was not too busy and averaged 6.8 patients (Ball and Pike 2009). The same survey revealed that the average patient-to-nurse ratio was 11 during the night and 8 during the day shift. NICE guideline for safe staffing for nursing suggested that there is no standard ratio of nurse-to-patient for all wards that can ensure safe patient care and that it depends on the individual ward's requirements. However, the guideline determined an evidence-based recommendation for safe nurses staffing to meet both nurse and patient needs (NICE 2014).

3.5.1.4. Shift patterns

Shift patterns, specifically night shifts and long shifts (i.e., 12-hour shifts); have also been identified as a major factor in the current study. A few nurses pointed to the increased frequency of errors during the day shift; however, other studies found that this might be because of the increased frequency of administered doses during the day or because of the higher rate of detection during the day shift.

Interviewees indicated that the risk of error increase during night shifts and long or 12-hour shifts when they were physically fatigued and sleepy, especially when associated with hunger and not taking adequate breaks. Although working long days is common practice for nurses in the study Trust during both day and night shifts, fatigue and sleepiness become more of an issue during the night shift because in the study trust, night shift nurses have to administer the morning dose of IVs before they leave, which is when their level of fatigue and sleepiness are expected to be high. Furthermore, the literature showed a significant association between working night shifts and poor or inadequate sleep of nurses, which in consequence may lead to both physical and mental fatigue among nurses. Ruggiero (2003) concluded that night-shift nurses had poorer quality of sleep compared with day shift nurses, while Geiger-Brown et al. (2012) showed that nurses' sleepiness toward the end of the shift was greater in the nightshift than the day shift. The relationship between inadequate sleep and increased level of fatigue among nurses due to extended working hours (i.e., 12 hours or more) has been demonstrated in previous research, especially if combined with shift rotations, inadequate recovery time, or working overtime (Trinkoff et al. 2001, Winwood et al. 2006, Stimpfel et al. 2012).

In addition, the association between working hours, fatigue and sleepiness levels of nurses and the rate of MAEs has been addressed by previous studies. Rogers et al. (2004) revealed that work duration has a significant effect on errors. The risk of making errors increased by three time when nurses worked 12.5 hours or more, or more than 40 hours per week. In another study involving 502 critical care nurses, Scott et al. (2006) studied the impact of shift patterns and length of shift on nurses' vigilance and the occurrence of medication errors. The findings of Scott's study supported the relationship between the extended working hours, decreased nurses' vigilance and increased number of reported errors. They concluded that the likelihood of reporting errors increased by double when nurses worked 12.5 hours or more.

As a result, the Joint Commission in 2011 released an alert to all hospitals to pay more attention to the risk of fatigue of healthcare professionals caused by long shift and to focus their efforts to address this issue. Nine evidence-based actions were recommended by the Joint Commission and involved "assessment of off-shift hours and consecutive shifts worked, and the inclusion of staff in the design of work schedules to reduce risk for fatigue" (Joint Commission 2011 p18).

3.5.2. Task factors

The most common task factor reported by the nurses was failure in the checking processes. Interviewees described inappropriate checking as a common practice, particularly when it came to checking allergy status, drug chart updates made by doctors, or with doses requiring double checking. Different causes were found to contribute to such practice. Nurses' reliance on their knowledge and experience, as well as the complacency of nurses looking after patients for a long period of time, were common factors discussed by interviewees. Error-producing conditions that can contribute to such practise included workload and short staffing which led nurses to perform the medication task under pressure. These findings are consistent with previous research. The issues around faulty checking during medication preparation and administration were frequently reported (Brady et al. 2009, Keers et al. 2013). However, few details were provided about the nature and origins of such practice. In Jones and Treiber (2010) study which involved 202 nurses, nurses reported, regardless of other factors, that not following the 5 rights was a very important contributing factor to medication errors. Using mixed methods, Tang et al. (2007) also found that nurses

believed "nurses' personal neglect" was one of the most common contributing factors to errors, and that preparing and administrating medicines without rechecking was a major condition of such personal neglect, especially with frequent interruptions. Although nurses are required to follow standard protocols and policies in order to safely administer medicines (Ashton and Iyer 2003), increased workloads and working under time pressures caused them to deviate from these protocols as time-saving strategies commonly used to manage their workloads, resulting in error-prone situations (Brady et al. 2009). The few studies that reported causes behind these violations suggested that violations of MA policies may arise from increased workload, familiarity with the drug or patient, and staff relationships (increased level of trust between nurses), particularly in cases of double checking.

Unclear or incomplete prescriptions were also reported as a factor related to the task and leading to a communication failure between nurses and doctors. This factor can be directly linked to other factors reported by some interviewees, such as the design of the drug chart. Small spaces provided in the drug chart, overwriting when the prescriber changed the prescription, and prescribing in the wrong place on the drug charts were all reported. Regardless of prescribing errors, poor written communication between nurses and doctors, including poor prescribing (mainly illegible, unclear, or incomplete prescription), have been identified by many researches as a widespread problem and common contributing factor for MAEs. In Gladstone's study, poor prescribing, including poor handwriting, was identified by nurses as a significant factor in MAEs (Gladstone 1995). According to a survey-based study conducted by Jones and Treiber (2010) and involving 202 nurses, illegible or unclear handwriting in the prescriptions was rated by 86% of nurses as a very important factor to medication errors. This led various institutions such as the British Medical Association and Royal Pharmaceutical Society 2001 to release guidelines for written prescriptions. Therefore, the prominent impact of poor quality of prescriptions indicates that quality of medication administration also depends on the performance of other healthcare professionals (Keers et al. 2013).

3.5.3. Team factors

In line with most previous studies, communication problems within the nursing team and with doctors were frequently raised by participants in this study as common

contributing factors to errors (Taxis and Barber 2003, Balas et al. 2004, Nichols et al. 2008). In both cases, most miscommunications occurred within the drug chart and led to frequent omissions and late administrations. In the case of nursing team, such errors were partly related to lack of or incomplete documentation in the drug chart when administering the medicine or when intentionally omitted, although a few nurses reported miscommunication (that is, not delivering complete information about the patients) between teams during the handover as well. In the case of miscommunication with doctors, the main issue participants raised was also related to the drug chart and involved doctors inappropriately prescribing or forgetting to notify nurses about updates.

One of the most important issues that emerged from different studies on medication safety was the need for effective communication between multidisciplinary teams, as many studies showed that miscommunication between multi-disciplinary staff may negatively affect patient safety and contribute to medication errors (McBride-Henry and Foureur 2007). Therefore, the strategies and interventions to improve medication safety should take into consideration improving the communication within the team and with multi-disciplinary teams. This may include structured communication tools. In the study trust, electronic administration has been introduced, and such system may play a role in improving communication problems recurring within paper-based drug charts. Furthermore, adherence to good practices of prescribing can play an essential role in avoiding prescribing and administration errors. Good or bad communications between healthcare professionals were found to contribute to both aetiology and prevention of MEs (Balas et al. 2004).

3.5.4. Patient-related factors

Different patient-related factors were reported. Respondents believed that patients with complex clinical conditions were at higher risk of MAIs due to either their ability to deteriorate quickly or because of the number of medications prescribed for them. Similar results were reported by many other researchers such as Tang et al. (2007) who indicated that patients with poor clinical condition commonly experienced errors during medication administration. Previous studies showed that patient acuity affected MAIs, either because of the complexity of those patients' prescriptions (Benner et al. 2002, Tang et al. 2007) or because of the extra load on nurses, usually added because of the

extensive care that they required or the high number of medications to be administered (Jones and Treiber 2010). Some research has associated patient acuity with increased frequency of interruptions and distractions, inadequate staffing levels, high workloads, and high levels of fatigue of nurses (Reason 2000, Balas et al. 2004, Keers et al. 2013). In the current study, nurses also stated the issue of misreading the drug chart of those patients because of the increased number of prescribed medicines, something which has not been discussed by other studies.

Confused and unconscious patients who are unable to communicate were also mentioned by many nurses in the current study as high risk patients. However, this was rarely uncovered by studies which focused on causes and contributing factors of MAEs, which means that further investigations of the risk of MEs on those groups of patients is necessary.

Our research, like others, indicated that patient behaviour and personality can also lead to errors during the medication administration process, usually due to non-cooperation (Hand and Barber 2000, Taxis and Barber 2003), non-compliance (Kim et al. 2011), or interrupting the nurses. In these cases, omissions and wrong timing errors are most common.

3.5.5. Personal factors

Inadequate knowledge, experience, and skills, such as mathematical skills of nurses, especially junior and bank agency nurses who may have limited experience, were reported during the interviews to contribute to errors during medication preparation and administration. This factor was recognised by many studies as a high-ranking contributing factor of MAEs (Gladstone 1995, Taxis and Barber 2004, Nichols et al. 2008, Chua et al. 2009) and was found by other studies which have used human error theory to have a strong link to nurses' knowledge and rule-based mistakes (Keers et al. 2013). Tang et al. (2007) found that around one third of nurses related their errors to being new and having limited experience. In errors associated with IV doses, Taxis and Barber (2003) observed nurses (n=113) preparing and administering IVs in two UK hospitals and showed that lack of knowledge and experiences of nurses caused 79% of observed errors.

Nurses' lack of knowledge often includes knowledge about the drug, disease, protocols and procedures of medication administration, and also their unfamiliarity with the area and equipment used. Some research extended the insufficient knowledge of nurses to universities' curricula and teaching of clinical pharmacology. Results from several studies around nurses' education showed a lack of adequate pharmacological knowledge among nurses, combined with insufficient continuing education from the hospitals (Brady et al. 2009).

Nurses' lack of experience was related to being new and to the low level of nurses' practical experience. According to Jones and Treiber (2010), nurses reported that errors mainly occurred at early stages of their nursing career. Reason (1995) stated that errors caused by inadequate individual knowledge can be limited by increase training. Moreover, several studies recommended extended training, especially for new staff, to strength the system and overcome the impact of nurses' lack of knowledge on medication administration safety (Prot et al. 2005, Tang et al. 2007, Brady et al. 2009, Ozkan et al. 2011). Therefore, overcoming inadequate training and lack of knowledge was considered an organisational or institutional responsibility and not only an individual factor (Ozkan et al. 2011). In the current study, nurses also highlighted the need for training and put the responsibility of their training on Trust management, further, they believed that training and education provided by the Trust was insufficient to administer medicines safely. This was further emphasised when interviewees talked about the continuous training provided to them and when they mentioned the inappropriate assessment of their intravenous drug administration skills. Thus, the factor of inadequate knowledge and experience of nurses suggests that providing adequate training, particularly for new nurses, by extending their training period can be a key way to meet nurses' needs and minimise MAIs.

Another element of nurses' individual knowledge and skills reported to be a common cause of MAEs is nurses' calculation skills. Despite nurses' calculation skills being considered a key nursing competency (Nursing Midwifery Council 2012), Wright (2007) and Fleming et al. (2014) identified a considerable insufficiency in both conceptual and mathematical skills among nurses which may affect their ability to calculate medicines doses accurately in the practice. In a recent UK-based study, 92% of student nurses and 89% of registered nurses failed the medicine calculation test

(McMullan et al. 2010). This led the researchers to recommend further education on "mathematical and conceptual drug calculation skills" (Fleming et al. 2014p 60) as a part of medication education in the nursing curriculum and continuous education programmes (McMullan et al. 2010, Fleming et al. 2014).

In terms of the role of nurses' calculation skills on medication errors, several previous studies reported nurses' poor calculation skills as one of the factors contributing to errors (Gladstone 1995, Deans 2005, Chua et al. 2009). However, a literature review conducted by Wright (2010) to identify whether there is a relationship between medication errors and nurses' poor calculation skills showed insufficient evidence to suggest this relationship between nurses' calculation skills and rate of medication errors, which suggests the need for further research on the calculation errors in practice, particularly among paediatric nurses. An explanation for this might be the use of technology, such as intravenous pumps with electronic drip-rate counters, which may contribute to reduced use of nurses' calculation skills (McMullan et al. 2010).

In this study, the few interviewees who identified poor nurses' calculation skills as a potential factor to MAIs, suggested that this factor become more influential when preparing small doses for paediatrics which may require complex calculations. This is similar to other research which found the likelihood of making errors due to inaccurate calculations of dosage was found to be more significant in paediatric doses which may be prepared in small amounts and require complex calculations (Brady et al. 2009, Ozkan et al. 2011).

3.5.6. Contributing factors associated with IV errors

The study results have shown that both individual and organisational factors can contribute to IV drug errors. The main issues identified included inadequate training, the complexity of some IV preparations, and the confusion with different routes of administration among ICU nurses. The complexity of some IV preparations, which require complex calculations such as paediatric doses, have been recognised as contributing to errors of inaccurate dose preparations and setting the wrong infusion rate. Our results confirmed previous studies' findings in terms of nurses' lack of training in preparing and administering IV medicines, although only limited studies specifically investigated the causes and contributing factors of errors in IV medicine

preparation and administration (Taxis and Barber 2003, Taxis and Barber 2004). Interviewees placed the responsibility of their training inadequacy and inappropriate assessment on the regulators and believed that the Trust needs to reassess the training approach provided to nurses before and after competency. Taxis and Barber (2003) added that pharmacists in wards can play an important role in recognising and addressing the training needs of nurses.

Previous research also identified the presentation of ampoules and the complex design of some equipment such as infusion pumps as factors related to manufacturers; however, such factors were not recognised by any of our participants. Several attempts were suggested to reduce errors in IV preparation, and one of them was to centralise IV preparations, but no significant evidence was identified for success of this initiative (Taxis and Barber 2003).

3.5.7. Type of ward in relation to factors contributing to medication incidents

In general, there was no indication of influence from the area in which nurses worked on the factors reported to contribute to MAIs, and nurses agreed on the general themes that emerged from the interviews. Nurses from intensive care units reported that interruptions and distractions were more problematic from colleagues than patients, as patients in ICUs are mostly unconscious, although unconscious patients were reported to be at higher risk of errors because of their inability to communicate.

When discussing their workloads, nurses working in ICU linked their heavy workload to patient acuity rather staffing levels as nurses from other directorates did. This may be because of the low nurse-patient ratio in ICU compared to other wards, as each nurse in ICUs is responsible to just one patient while the ratio in other wards may reach six or seven.

Finally, when nurses discussed the feedback provided to them about MIs that occurred, this also seemed to differ from ward to ward; for example, nurses from Abdominal, and surgery directorates did not consider this as a factor and mentioned that they were receiving regular feedback from ward management, while interviewees from other directorates considered learning from reported errors is limited because of absence of

feedback. This may be because senior nurses and ward managers in areas such as Abdominal, and surgery directorates were more proactive in providing their staff with such information about reported errors on a regular base. However, almost all nurses interviewed believed that receiving feedback is important and that more feedback on errors would be helpful.

3.5.8. Limitations of the study

A few limitations were identified in this study. As with all qualitative interview-based studies, the small sample size may limit the extent of our results. However, because no new themes emerged in the final interviews, the sample size might be sufficient for the purpose of this study. In addition, there are significant similarities between the findings of our study and earlier ones on that used either qualitative methods or different methodologies to report on factors contributing to MAEs.

The study's second limitation was that it was conducted in only one trust. Therefore, nurses' views may be limited to the study site and may not be generalisable to other sites. However, as many participants had previously worked in other hospitals, they may have provided diverse views that minimise this limitation.

Another limitation is that nurses' views may reflect the ward or directorate in which they work and may not apply to other areas. However, the study sample involved nurses from a wide range of departments, grades, and levels of experience, thus these variations reflect the diversity of nurses' and midwives' backgrounds. Furthermore, the views and opinions discussed by interviewees were not influenced by the area the nurses lived in nor their years of experience or grades. The nurses were in general agreement about the main factors that contributed to MAEs.

Another potential limitation of the study is that some interviewees were nurse managers and therefore subject to desirability bias (i.e., "participants tendency to present a favourable image of themselves") (Van de Mortel 2008 p102). Such bias may lead to a modified response about MAIs in their areas because these nurses were in the position of responsibility and therefore tended to talk positively about their wards' environments and staff. Staff nurses as well might have tried to speak positively when the discussion was about their individual or personal factors. However, we believe that this had a

limited influence as participants were informed about the benefits of such research in improving medication safety and they were encouraged to suggest suitable solutions. This helped nurses to feel more comfortable when discussing this sensitive topic. In addition, many personal issues that contributed to errors, such as inadequate levels of knowledge and training, were volunteered by the interviewees themselves.

3.5.9. Further work

As this study and published literature indicated that the causes and contributing factors are interrelated, further studies are recommended to explore the nature and role of each factor leading to MAIs and to provide better understanding of how these factors are related. Future research should also focus on set interventions which could result in significant and long-lasting improvements in medication safety.

Interruption and distractions were the most common contributors to MAIs. They have been reported in almost all studies that investigated the causes of MAEs. However, limited information is available about interruption and distractions aetiology and sources and whether they combines with other factors such as workload and staffing levels. Thus, more research is needed to discover the role of this factor in MAIs' causation.

Many interviewees in this study acknowledged the problem of miscommunication between nurses, particularly poor documentation on drug charts, that contributed to omissions and delays in administrations. Errors due to miscommunication included documentation errors in which it was unclear when a dose had been given or whether a dose had been given at all. If medicine had not been administered to a patient, documentation sometimes did not specify the reasons why. Documentation problems perhaps could be improved by introducing an electronic administration system, which had already been activated in some areas of the study trust. Further studies should assess whether an electronic administration system improves the rate of documentation errors and reduce omissions and wrong timing errors.

Another factor in MAIs identified in this study and others was low staffing levels and skill mix especially in areas with a high number of bank or agencies' nurses. Such nurses may have insufficient training; some may not be permitted to prepare and

administer IVs. Several studies demonstrated the negative influence of nurses' workload and staffing levels on medication safety. These studies also showed that an increased level of staffing, particularly of experienced staff, was associated with better patient outcomes and reduced medication errors. However, only a few American and Canadian studies identified a relationship between the proportion of registered nurses and medication errors using secondary data analysis. Therefore, staffing levels needs to be taken into consideration by nurses' managers and institutional management. Further research with more robust methods is needed to investigate whether there is an optimum staffing level for different wards, taking into consideration the patients' factors (i.e., acuity and dependency) and shift patterns. Further work is also needed to quantify the relationship between the proportion of registered nurses (experienced nurses) within a team and the rate of medication administration errors. Patients' nursing care needs also must be factored into that relationship.

Interviewees in this study identified the lack of adequate training and assessment provided by the Trust as an issue. For example, nurses reported a need for more training in the practical side of IV preparation and administration, which led them to learn from each other. However, nurses may learn bad practices from each other, such as deviation from guidelines which may become accepted (Taxis and Barber 2003). Therefore, ensuring that nurses receive the training they need is essential, by extending the training provided to them particularly for new nurses. Improving nurses' knowledge and skills would enhance patient safety and reduce risks. This can be achieved by reassessing the competency test that nurses undergo before they are allowed to administer medicines. Continuouse education programs for nurses should also be considered to ensure that nurses' knowledge of medicines is up to date. A senior nurse interviewed also emphasised the importance of re-assessing nurses' competency for administering IV doses at regular intervals to ensure their eligibility to do medication tasks. Further work is needed to evaluate the training approaches set in the Trust and measure their impact on nurses' knowledge and skills.

Nurses indicated that they are more likely to make errors due to fatigue and sleepiness particularly during night and long shifts. As long shifts are common practice in many organisations and in the study trust, assessing the impact of fatigue and sleepiness during long shifts on the rate of MAEs is essential to evaluate the risk to benefit

balance of such practice. Although some studies addressed this association, to date most of these studies relied on reported errors, or questionnaires to nurses. There is as yet no quantitative research that investigated this relationship in the form of observational studies. Observational studies are considered the gold method for gathering data about MAEs. Therefore, further work using direct observation is needed to better assess the effect of nurses' fatigue and sleepiness during long hours of nurses on MAEs.

3.6. Conclusion

Medication preparation and administration are frequent, high-risk tasks in the nursing profession. The literature showed that medication errors during the administration stage were common. The objectives of the semi-structured interviews in this study were to identify what nurses believed about the causes and contributing factors of MAIs and how those factors could be reduced. Such research was not available in the study Trust before conducting this study. The study results revealed that MAIs have multiple causes and interrelated factors that can contribute to errors. The contributing factors of MAIs can be personal, managerial or organisational factors. Therefore, both organisations and individual nurses share responsibility to ensure safe medication administration to patients. Identified factors concerned the work environment (e.g., heavy workload, insufficient staffing, interruptions and distractions, and shift patterns), the task of medication preparation and administration (mainly prescribing quality, and inappropriate checking), patients (acuity of conditions, patients' personalities, communication and language barriers), individual nurses (lack of knowledge, unfamiliarity with the area or medications, and physical health problems such as fatigue and sleepiness), problems within teams (mainly lack of communication or miscommunication between nurses or with doctors, supervision, lack of or over-confidence of nurses), and institutional factors (insufficient staff training, lack of feedback about medication errors). This study confirmed the main factors identified earlier in the literature. To improve the safety of medication administration, the identified issues need to be addressed. Future research should investigate the nature and contribution of each of the emerging factors to help prioritise the efforts to reduce MAI rates. The most important contributors need to be determined as well as which interventions may result in long-lasting improvements in medication safety.

Chapter 4. The Impact of Nurses' Fatigue and Sleepiness on Intravenous Preparation and Administration

4.1. Introduction

4.1.1. Background

Increased PSIs and worker injuries have been recognised as serious challenge within the healthcare organisations (Kohn et al. 2000, Treanor 2000). Nurses are strongly associated with the quality and safety of healthcare because of their role in providing direct patient care (Tourangeau et al. 2006). Furthermore, nurses are more commonly exposed to occupational injuries and illnesses compared with other healthcare workers (Smedley et al. 1997, Trinkoff et al. 2002). The specific critical causes and contributing factors leading to safety incidents and decreased performance may vary within different healthcare domains (Barker and Nussbaum 2011). However, studies of the factors contributing to medication errors identified many factors linked to work conditions. Among these were shift patterns, heavy workloads, frequent interruptions, and low staffing levels (Armitage and Knapman 2003, Brady et al. 2009). The working hours of nurses were considered by the IOM as a potential risk to patient safety. The IOM specifically commented on the potential impact of fatigue that may cause reduced attention to detail, slow reaction times, omission errors, decreased energy, and lack of motivation (Child et al. 2004) .

4.1.2. Working conditions

Providing 24-hour nursing care inevitably requires nurses to work different shift patterns including "long days" or 12-hour shifts (Newey and Hood 2004, Lorenz 2008). Long shifts have become common practice across different industries including healthcare organisations (Ball and Pike 2009, UNISON 2015). However, there are concerns about the impact of long shifts on nurses' fatigue, stress, performance, and on patient safety (Ball et al. 2015). Traditionally, daily shift patterns consisted of three eight-hour shifts (Estabrooks et al. 2009). However, over the past 20 years, working pattern have altered in preference to the 12-hour shift. Long-hour shifts are currently widely used in UK nursing practices with many hospitals adopting long-hour shifts as the primary pattern (Ball et al. 2015).

The main advantages of long shifts are based on cost effectiveness in providing 24-hour care, and the ability to provide a greater continuity of staffing and patient care (Estabrooks et al. 2009). Long shifts also enable staff to have more off time and has

been shown to increase job satisfaction (Trinkoff et al. (2006). Jones and Brown (1986) surveyed a sample of 15 North Carolina hospitals to evaluate the objectives of 12-hour shifts. The objectives identified included: increase continuity of patient care, increased staff cohesiveness, reduced rate of absenteeism, additional off days for nurses, and reduction in the number of staff and recruitment costs for the hospitals. The perception of nurses regarding 12-hour shifts was elicited by McGettrick and O'Neill (2006), who surveyed 80 critical care nurses in a large NHS hospital. Nurses identified the continuity of care in 12-hour shifts and the opportunity to plan care enhanced patient care. Job satisfaction, and increase off-duty time were other advantages if the shifts were well managed. In contrast, fatigue and feelings of tiredness were the most negative responses from nurses. Josten et al. (2003) investigated the advantages of extended work shifts among 134 nurses working in three nursing homes in the Netherlands. A questionnaire, was used to evaluate the fatigue, performance, and satisfaction of nurses. They reported that they preferred long shifts as they could work fewer shifts and had more off-duty days. Nurses also commented that extended shifts were associated with higher fatigue levels at the end of the shifts as well as higher need for recovery between shifts (Josten et al. 2003).

Concerns have increased about the potential risks of long shifts on the quality of patient care and safety (Stimpfel and Aiken 2013). Therefore, some employers have questioned the benefits of such extended hours (12 hours) rather than eight-hour shifts (Geiger-Brown and Trinkoff 2010).

4.1.3. Prevalence of 12-hour shifts

Several studies explored the prevalence of working 12-hour shifts among nurses. A survey-based study by Ball and Pike (2009) found that 41% of NHS hospital and 63% of care home nurses regularly worked 12-hour shifts. A UK, survey by UNISON (2015) showed that the number of nurses working long shifts increased from 2013, with around one-third (32%) of nurses worked a long day in 2015 compared with 18% in 2013. The survey also revealed that around half (47%) of respondents worked a shift that was already contracted to last for 10 hours or more. Of those shifts, 26% were scheduled to last 12 hours or more.

In the US, Trinkoff et al. (2006) surveyed 2,273 nurses about their work schedule and hours worked per day and per week. The study found that 19% of hospital nurses were working more than 12 hours per day. This percentage was even greater in adult critical care units (36%), paediatric critical care units (27%), and emergency departments (26%). A-third of nurses worked more than 40 hours per week. Of all nurses, those in hospitals were most likely to work long shifts but less likely to work more than five days per week. In another US study by Stimpfel and Aiken (2013), 65% (1, 4370) of nurses reported they regularly work 12-13 consecutive hours per shift. Kalisch and Lee (2013) found that among the 3,769 nurses from 95 units within six hospitals surveyed, 59% (2230) worked 12-hour shifts, 30.5% (1150) worked 8 hours, 4.3% (163) worked 10 hours, and 5.1% (191) worked rotating shifts.

Across Europe, considerable differences have been noted. A European cross-sectional study of 31,627 nurses from 2,170 general medical and surgical units in 487 hospitals was undertaken by Griffiths et al. (2014). This study found that 50% (15,930) were working less than eight-hour shifts, 30% (9,963) worked 8-10 hour shifts, and only 14%(4,314) worked 12-13 hour shifts. This pattern is different from that in the UK, Ireland and Poland, where 12-hour shifts were common.

4.1.4. Impact of long shifts on nurses and patient outcomes

Several studies examined the outcomes associated with long shifts, including nurses' fatigue, stress and burnout, job/career satisfaction, occupational injuries, and performance. As shift work is common practice in many industries, fatigue associated with working long shifts has been linked with disasters such as the Three Mile Island and Chernobyl nuclear plant accidents, and the grounding of the Exxon Valdez oil tanker (Ball et al. 2015). A systematic review by Smith et al. (1998) compared 8-hour and 12-hour shifts across a range of industries. The review concluded that working long shifts (12 hours) was associated with increased fatigue levels compared to shorter shifts (8 hours). However, longer shifts improved job performance. Among healthcare professionals, fatigue levels were found to increase over the shift period. Extended shifts (9-12 hours) were found to a risk of accumulation of fatigue (Poissonnet and Veron 2000). Geiger-Brown and Trinkoff (2010) reviewed nursing practice studies and concluded that 12-hour shifts were associated with increased fatigue, drowsy driving, and sleep deprivation compared to shorter shifts. In another study of 134 nurses who

completed self-rating questionnaires on fatigue, satisfaction, health, and quality of care they provide, Josten and colleagues (2003) linked extended nurses' shifts of nine hours with increased levels of nurses' fatigue, and more health problems. A decrease in the quality of care nurses provided compared to 8-hour shift was also identified (Josten et al. 2003). Furthermore, Trinkoff et al. (2001) noted increased levels of fatigue among nurses working long shifts because of excessive exposure to both physical and mental demands, especially if long shifts were followed by inadequate recovery time.

One of the concepts linked to fatigue and shifts schedules is the need for recovery from fatigue caused by work. Increased daily and weekly working hours usually means that greater recovery from work is needed. Workers were found to need more time for recovery when they worked long hours, night shifts, or work overtime (Jansen et al. 2003, Winwood et al. 2006). Long and irregular work shifts such as weekends or those requiring overtime and/or rotation worked by nurses were associated with adverse effects and reduced recovery time between shifts. The impact of these shifts increases if nurses do not get enough sleep between shifts (Winwood et al. 2006).

In a survey-based study involving 22,275 nurses from 557 US hospitals, Stimpfel et al. (2012) showed that nurses working ten hours or more were two-and-half times more likely to suffer from burnout and job dissatisfaction compared to those working shorter shifts. Furthermore, patient dissatisfaction, assessed using a survey about their experience during their hospital stay, coincided with the increase in the percentage of nurses working thirteen hours or more per shift. Another study by Stimpfel and Aiken (2013) revealed that during 12-hours or longer shifts, nurses were significantly more likely to report poor quality of care and poor patient safety compared with eight-hour shifts.

Fatigue is one factors specifically linked to stress, decreased performance and safety in different work environments (Winwood et al. 2006, Barker and Nussbaum 2011). Within the nursing profession, fatigue was found to be a factor in nurses' injuries, adverse health consequences, and work dissatisfaction (Josten et al. 2003, Geiger-Brown et al. 2004). Nurse fatigue has also be linked to absenteeism (Rogers et al. 2004), decreased performance (Barker and Nussbaum 2011), and reduced patient safety (Rogers et al. 2004, Barker and Nussbaum 2011). Moreover, increased working hours

and fatigue were found to be potential contributing factors for occupational injuries (Dembe et al. 2005). When combined with work-related stress, fatigue was found by Trinkoff et al. (2002) and Smith et al. (2003) to be associated with disorders of the neck, shoulders, and knee musculoskeletal and back pain among nurses. Studies have demonstrated that increased fatigue and sleepiness levels among nurses were associated with reduced reaction times, lapses, reduced motivation, and reduced energy which contributed to errors and omissions made by nurses during tasks (Rogers et al. 2004, Carroll 2005, Scott et al. 2006).

Following these studies, the IOM recommended that nurses should not work more than 12 consecutive hours per shift and not more than 60 hours per week (Trinkoff et al. 2006). In 2011 the Joint Commission issued an alert to all hospitals to focus more efforts on managing the risk of fatigue caused by long shifts. The Joint Commission recommended that in order for hospitals to reduce the risk of fatigue among healthcare professionals, they should regularly assess the off-shift hours as well as consecutive shifts worked (Joint Commission 2011). In addition, to ensure the safety of both the nurse and patient, the American Nurses Association (ANA) recommended that individual nurse should be provided with:

"A work schedule that provides for adequate rest and recuperation between scheduled work; and sufficient compensation and appropriate staffing systems that foster a safe and healthful environment in which the registered nurse does not feel compelled to seek supplemental income through overtime, extra shifts, and other practices that contribute to worker fatigue" (American Nurses Association 2008, p 1).

At the same time, the ANA recommended that:

"regardless of the number of hours worked, each registered nurse has an ethical responsibility to carefully consider his/her level of fatigue when deciding whether to accept any assignment extending beyond the regularly scheduled work day or week, including a mandatory or volunteer overtime assignment" (American Nurses Association 2008, p 1)

4.1.5. Fatigue and sleepiness among nurses

Fatigue has been described as a:

"*multicausal, multidimensional, nonspecific, and subjective phenomenon which results from prolonged activity and psychological, socioeconomic, and environmental factors that affect both the mind and the body*" (Tiesinga et al. 1996, p 64).

Occupational fatigue was frequently described as acute fatigue, although many definitions of occupational fatigue do not distinguish between chronic and acute fatigue (Winwood et al. 2005). Nurses perceived higher levels of acute fatigue than chronic fatigue (Winwood et al. 2006). However frequent exposure to acute fatigue caused by long shifts with insufficient recovery time means nurses are likely to suffer from chronic fatigue (Josten et al. 2003, Winwood et al. 2006). Therefore, both acute and chronic fatigue should be considered when quantifying levels of fatigue within a nursing population (Barker and Nussbaum 2011).

Previous studies have suggested that fatigue is multifactorial and that different biological, psychological, and social factors can contribute to fatigue. Biological factors, e.g. sleepiness, and psychological factors e.g. anxiety and depression, in addition to other demographic and work-related factors, e.g. gender and shift work, were found to have an influence on fatigue levels (Ruggiero 2003). Ruggiero (2003) examined the contribution of depression, sleep quality, and anxiety to levels of chronic fatigue among ICU nurses. The study revealed that poor sleep quality and depression significantly contributed to chronic fatigue. Sleep disturbances and depression were most common among night shift nurses compared with nurses working day shifts.

In a study of fatigue prevalence among general shift workers in the Netherlands, Jansen et al. (2003) used self-reported questionnaires administered to 12,095 workers. The study found that around 20% of shift workers suffered from fatigue. While in nursing, Kunert et al. (2007) examined the sleepiness and fatigue level among 2,025 nurses using two validated scales. The study identified that both fatigue and sleepiness were common in nurses working both day and night-shifts. However, nurses working night-shift reported higher fatigue levels and poorer sleep quality than nurses undertaking day-shift.. This study suggested that implementing interventions to enhance sleep quality

and reduce fatigue is essential for nurses to provide safe and competent patient care. An Australian study involving 23 registered nurses used self-reported logbooks to collect error data and information about their symptoms of sleepiness. Nurses reported 22 errors and reported that they were struggling to keep awake during one-third of shifts worked (Dorrian et al. 2006).

An online survey of 745 US registered nurses using several fatigue scales was conducted by Barker and Nussbaum (2011). This study evaluated the perceived levels of fatigue dimensions (mental, physical and total fatigue, together with acute and chronic) among registered nurses and examined the relationships between these different dimensions and nurse performance. Nurses reported increased levels of mental, physical and total fatigue. The OFER scale, which measures acute and chronic fatigue, showed that the nurses perceived significantly higher levels of acute fatigue than chronic fatigue. Different factors were associated with chronic fatigue. These included: sleep hours per night, total hours worked every week and type of shift worked. Acute fatigue was significantly associated with hours of sleep per night, shift length and work schedules (Barker and Nussbaum 2011).

4.1.6. Long shifts and patient safety

The impact of long hours on the incidence of medical errors was studied among residents (Landrigan et al. 2004). Residents were assigned to work either traditional shift lengths or shorter shifts. The study concluded that residents assigned traditional shifts made 36% more errors than interns who worked shorter shifts. Among nurses, long working hours was considered a risk to patient safety. The evidence report summaries of the Agency for Healthcare Research and Quality (AHRQ) considered there was sufficient evidence to conclude that some working conditions affected the occurrence of medical errors. These working conditions involved workforce staffing, e.g. the workload allocated to staff, skills and training required, level of experience, and impact of work schedules (Agency for Healthcare Research and Quality 2003). The AHRQ also conducted a comprehensive review to evaluate how nursing staffing and nurses' working hours affected hospital patient outcomes. This review concluded that increased nurses' working hours per patient day was associated with reduced patients' mortality, morbidity, and occurrence of AEs. The study also identified the need to assess the impact of work hours on patient safety (Kane et al. 2007) .

Few studies have assessed the impact of nurses' shift lengths on medication safety. Rogers (2004), used 14-day logbooks completed by nurse to collect data on time, and length of shifts worked together with a full description of any errors and near errors that occurred during their shifts. The study involved a sample of 393 nurses who were generally working more than 40 hours each week. Results showed that the risk of error significantly increased with increased shift length, overtime, and when the nurses' total weekly time worked exceeded 40 hours. The probability of making errors during shifts of 12 hours or more was three times higher compared to 8.5 hour shifts. More than half of the 199 errors (58%) and 213 near errors (56%) reported involved MAEs.

In another US study involving a random sample of 502 critical care nurses, nurses used logbooks to record information about the type and duration of shifts worked, overtime, sleeping patterns, and any errors or near errors that occurred during their shifts (Scott et al. 2006). The study revealed that 44% of critical care nurses were scheduled to work 12.5 hours or more per shift with 62% actually worked shifts of 12.5 hours or more. The study also revealed that 61% of the nurses worked ten or more overtime shifts during a 28-day period. The study identified that working 12.5 consecutive hours or more, or working more than 40 hours per week, doubled the risk of a nurse making error compared to when they worked 8.5 consecutive hours or less. In addition, increased shift length was associated with reduced vigilance by nurses and increased drowsiness and sleepiness during a shift. Again, most (56.5%) of the 224 errors reported were MAEs.

In a case study involving six nurses from a neonatal ICU, nurses self-reported three MAEs and three procedural errors. The nurses involved mentioned that lack of sufficient sleep, and reduced alertness were factors which contributed to errors in all cases. The study concluded that nurses are required to "be alert enough to provide safe care for their patients…and alert enough to detect and correct the errors made by others" (Dean et al. 2006, p.123).

In summary, these studies have identified that long nursing shifts are associated with increased incidence of errors because of the effect of fatigue and sleepiness on nurses' accuracy during medication preparation and administration. In the study trust, night shift nurses commonly administer the morning doses of IV medications at the end of

their shift when sleepiness and fatigue is anticipated to be high, as discussed above. Furthermore, interviews with Trust nurses and midwives suggested that long shifts (12-hour shifts) and night shifts could be important contributors to MAEs. Interruption and distraction was the most common contributing factor beside increased workload and long shifts. However a number of studies have investigated the different interventions employed to manage interruptions during medication administration and no significant evidence has been identified to support their effectiveness. In addition, Raban and Westbrook (2014) in their systematic review concluded that in order to provide evidence of effectiveness of intervention targeting interruptions to nurses, further research need to be controlled randomised or cluster randomised studies across multiple sites. In addition, to date, only studies involving questionnaires and self-reported logbooks have been employed to evaluate the impact of long working hours on the safety of medication preparation and administration but medication preparation tasks have not been used. Therefore, quantitative observational research is required to evaluate the effect of long working hours on nurses' fatigue and sleepiness, and on the occurrence of MAEs which could be undertaken at a single site.

4.2. Study aim and objectives

4.2.1. Study aim

To investigate whether nurses' fatigue and sleepiness during long shifts (12-hour shifts) have an impact on the rates and types of errors during IV preparation and administration.

4.2.2. Study objectives

- To determine the baseline chronic and acute fatigue of nurses working 12-hour shift as well as their recovery experiences between these shifts.
- To determine the relationship between nurses' work hours and the occurrence of errors during simulated IV preparation and infusion rate setting tasks.
- To determine the relationship between nurses' work hours and nurses' deviations from the best practice during simulated IV preparation and infusion rate setting.

- To assess the differences in nurses' sleepiness at the beginning, 8 hours and at the end of a 12 hour night shift.
- To determine the relationship between sleepiness and the occurrence of errors during simulated IV preparation and infusion rate setting tasks undertaken at the beginning and end of a 12 hour shift.

4.3. Methods

4.3.1. Study design

An observational study of IV preparation and administration errors was conducted using simulated tasks for nurses assessed during night shifts (8pm to 8am). This study required observing nurses preparing the tasks and setting the infusion pump for administration of the prescribed dose, at the beginning of their shift and again at the end of the same shift. In additions, fatigue and sleepiness were measured using validated questionnaires. Background fatigue was assessed at the beginning of the night shift, with sleepiness assessed at three points during the shift (beginning of shift, eight hours after start, and end of shift).

Direct observation is considered the 'gold standard' for collection of data on the incidence and nature of MEs (Allan and Barker 1990, Dean and Barber 2001, Flynn et al. 2002). This technique dates back to the early 1960s, when Barker and McConnell (1962) used this in medication error research. In this technique, the observer accompanies staff during the preparing and administration of medication to record details involved in the process. Direct observation was found to be the most effective and reliable technique in detecting MEs, particularly during the administration stage of the MUP, compared with other methods, which were found to underestimate the true incidence of errors (Barker and McConnell 1962, Flynn et al. 2002). Flynn et al. (2002) found that, among 2,556 doses, 300 MEs (11.7%) were detected using direct observation, compared to only 17 (0.7%) detected by record review and one (0.04%) identified by incident report analysis.

Many advantages of using observation technique in medication error research have been identified compared with other methods such as analysing legal and voluntary incident

reports, chart reviews, and using laboratory tests to check drug levels in urine or blood. The objectivity of direct observation overcomes other methods' limitations, such as unawareness of the error occurrence, unwillingness to report, and difficulty remembering to report during periods of high workload, which are considered to be the main causes of underreporting incidents. Therefore, in the observation technique, MEs are detected independently, regardless of the awareness of the people who made the error (Allan and Barker 1990). In addition, direct observation enables the observer to collect additional information which can be useful in identifying causes and factors contributing to errors although it focuses on the "sharp end" or on the care providers instead of latent conditions and the entire system of delivery (Thomas and Petersen 2003).

The impact of the observer is considered one of the main limitations of the observation technique (Allan and Barker 1990, Thomas and Petersen 2003). However, Dean and Barber (2001) examined the potential effect of observation on medication administration error incidence and found that the proportion of documentation of reasons for omitting drugs was the same during observation and non-observation periods and, therefore, observation had no effect on the incidence of omission errors during the administration process (Dean and Barber 2001).

4.3.2. Study settings and sample size calculation

The study was conducted in medical and surgical wards, and ICUs at one large acute teaching Trust (section 3.3.1). A total of 39 nurses from medical wards, surgical wards, and ICUs were selected to take part in this study. The sample size was calculated based on the assumptions that 25% of nurses will report high levels of sleepiness at the end of their shift (Geiger-Brown et al. 2012), and that the baseline human error probability in a drug preparation task is 3% for nurses (Garnerin et al. 2007). An assumption was also made that error rate would increase.

This study tested the hypothesis that nurses reporting high levels of sleepiness would be more likely to commit an error during a simulated drug preparation task. As an initial study and because of the lack of published literature linking the relationship between the two variables, assumptions were made. One assumption was made that the error rate would increase by 40% i.e. from 3% to 43% at the end of the shift. When both

variables, sleepy and not sleepy AND error or no error were treated as dichotomous variables, and based on chi-square test, 39 nurses were needed to find a statistically significant association.

4.3.3. Simulated drug preparation tasks

The simulated drug preparation tasks were developed in collaboration with a specialist pharmacist responsible for the safety of injectable medicines at the study hospital. Both tasks were chosen to provide a comparable degree of difficulty on preparation across study wards and challenge capacities on a fatigue status but reflect real life situations.

Each participant was asked to prepare an infusion at the beginning and at the end of the shift. These were:

a. Amphotericin liposomal 145mg infusion: This drug is not frequently prescribed and requires a calculation for dose and dilution, use of part vials and administration via an infusion pump.
b. Magnesium sulphate 10mmol infusion for peripheral administration: Although magnesium is more frequently prescribed, the usual dose was different to the dose used in the study. Preparation of the infusion required a calculation, dilution to specific minimum volume for peripheral administration, use of part vials and administration via an infusion pump.

4.3.4. Tasks allocation

Nurses were randomly assigned to two groups using block randomisation: Group A prepared magnesium at the start of the shift and amphotericin at the end of shift, and Group B prepared amphotericin at the beginning of the shift and magnesium at the end.

4.3.5. Development of data collection tools

4.3.5.1. Occupational Fatigue Exhaustion Recovery (OFER)

The participants' fatigue levels were measured using the Occupational Fatigue Exhaustion Recovery (OFER) scale (Winwood et al. 2005). This scale consists of three subscales measuring occupational chronic fatigue, acute fatigue, and inter-shift recovery. It consists of 15 items, and based on the fatigue and strain experienced at work and home. Responses are given using a seven-point scale (ranging from 0 = strongly disagree to 6 = strongly agree). OFER scale was developed to measure acute

fatigue, chronic fatigue, and inter-shift recovery in workers. This scale was chosen because it has been used and validated in healthcare workers, specifically nurses, and was found to have high reliability and to be gender independent (Winwood et al. 2006). Furthermore, it can differentiate between fatigue states (acute and chronic) and measure the recovery from fatigue between shifts (Winwood et al. 2005, Winwood et al. 2006).

4.3.5.2. Karolinska Sleepiness Scale (KSS)

The Karolinska Sleepiness Scale (KSS) was used to measure participants' sleepiness. This measure, developed by Akerstedt and Gillberg (1990), is a single-item scale of sleepiness (1 = "very alert" to 9 = "very sleepy-great effort to keep awake, fighting sleep"). The KSS has been validated to measure subjective sleepiness in occupational studies. It has been also used to measure nurses' sleepiness over 12 hour shifts (Kaida et al. 2006, Geiger-Brown et al. 2012). The KSS was used because it allows measurement of sleepiness state, i.e. sleepiness at a particular time during the day (Shahid et al. 2010). Participants in this study were required to record their level of sleepiness at the beginning of the shift, at eight hours, and at the end of their shift to assess differences in nurses' sleepiness between the end of 8 hours shift and 12 hours shift. In this study, a score greater than seven was considered to be a high level of sleepiness (upper one-third of the scale range) (Akerstedt and Gillberg 1990).

4.3.5.3. Study poster

The study poster (Appendix 8) was developed and displayed in nurses' clinical areas to invite them to participate in the study. The poster included brief information about the aim of the study and the anticipated inclusion criteria for participants. The poster also provided participation instructions for nurses interested in this study. In addition, the contact details for the research team were provided in case the nurses required further study information.

4.3.5.4. Selection questionnaire

A selection questionnaire (Appendix 9) was developed to identify and select eligible nurses. The questions were developed to collect the required information to identify eligible participants according to Oppenheim (1992)'s specifications. This career questionnaire consisted of two sections. The first section obtained information about the participant's current job and job title, grade, ward or department where the participant

worked, years of practice as a registered nurse, and shifts worked,. The second section obtained the participant's contact details.

4.3.5.5. Participant information leaflet

A participant information leaflet was developed to provide the participants with detailed information about the study (Appendix 10). The leaflet provided information regarding the background and aim of the study, eligibility requirements for participants, a description of the recruiting process, the potential benefits that would be acquired from the research, any possible risks, the participants' rights, anonymity, and confidentiality, plans for publication, and contact details of the research team in case the participant required any further information.

4.3.5.6. Consent form

A consent form was developed to be read and signed by participants before participation (Appendix 11). The consent form was provided along with the information leaflet with enough time to allow participants to read all the information provided. The consent form consisted of statements about the participant's agreement to participate and use of data collected during observation or from the questionnaires. Each participant was provided with a copy of the consent form to keep for reference. At the end of the form, the contacts details of the research team were again provided.

4.3.5.7. Pre-shift questionnaire

A pre-shift questionnaire was developed for completion by the participants at the beginning of the participation shift before they began the simulated preparation (Appendix 12). This questionnaire was developed to collect some additional demographic and work-related information and consisted of three sections. The first section contained career-related information, including the length of the participant's usual shift, total working hours per week, average hours of sleep during each 24-hour period over the seven days before participation, and whether the participant had any additional paid employment other than the current nursing job in the study hospital. The second section collected demographic data about age, marital status, and the highest educational degree of the participant to evaluate if there was any relationship between fatigue levels and demographic and work characteristics. The last section of the questionnaire contained the fatigue and sleepiness scales, where participants were asked

to score their acute and chronic fatigue and intershift recovery in addition to their current sleepiness at the beginning of the shift.

4.3.5.8. Shift diary

A one-page shift diary (Appendix 13) was developed and given to participants to allow them record any breaks and/or naps taken during the study shift. The diary also included a sleepiness scale to be self-completed by the participant at eight hours.

4.3.5.9. Post-shift questionnaire

The post-shift questionnaire (Appendix 14) was developed for completion by participants at the end of the shift and just before they began the post-shift observation task. The questionnaire was used to collect information about the participation shift, including the number of patients the participant was responsible for and any additional responsibilities assigned during the participation shift other than direct patient care. The final section of the questionnaire, allowed participants to score their sleepiness at 12 hours.

4.3.5.10. Observation instrument

The observation instrument (Appendix 15) was used by the observer as a checklist during observation. This observation instrument was developed from the Trust Injectable Medicines database (Medusa) and the Trust guideline for administration of medicines (Trust Drug and Therapeutics Committee 2015). The instrument consisted of 23 points (Table 4.1) representing the IV preparation and administration steps, beginning with reading the prescription to writing the label and preparing the pump with the appropriate infusion rate. These points were divided into four main sections. The first section involved the steps performed before preparation, such as checking expiry dates and selecting infusion fluids. The second section, involved all preparation process steps, ranging from conducting the calculation to completing the preparation and checking the medicine against the prescription. The third section, involved setting the infusion rate, and requesting the final independent check used in the administration process. A fourth section collected data about whether the nurse prepared an infusion label for the final product, and if any of the label fields contained omitted or incorrect information. Failures in steps 1-3, 6-7, 9, 11 13-14, 16-19, and 21-23 were considered deviations from best practice, while failures in steps 4-5, 8, 10, 12, 15, and 20 were

considered errors. The observation instrument was also used to record the time needed (in minutes) to complete the task.

Table 4.1. Steps assessed in the observation instrument

Before preparation
Reading and checking the prescription before start
Washing hands
Wearing gloves
Selecting correct diluent
Selecting correct infusion fluids
Checking expiry date
Assessing product integrity
Preparation process
Performing calculations
Disinfecting the vial
Using correct solvent volume for reconstitution
Shaking the vial after adding the solvent
Using correct drug volume
Request independent check before dilution
Using a filter and change the needle
Using correct volume of infusion fluid
Mixing after adding the drug
Assessing appearance of the final product
Checking the medicine against the prescription
Retain vials/ampoules for checking purposes
Administration process
Setting up the correct infusion rate
Request independent check
Labelling
Labelling the preparation
Complete and correct labelling information

4.3.5.11. Simulation prescriptions

Simulated prescriptions were provided to the participants as images of prescriptions from the electronic prescribing systems used in each ward (Appendix 16). These prescriptions contained all the standard information usually contained in real prescriptions, including the medication name, dose and route, and patient allergies. The prescription screenshots were accompanied by a cover letter with general instructions about the task to be read by the participant before beginning the preparation task.

4.3.6. Research permission

Ethical approval from the Biomedical Sciences, Dentistry, Medicine and Natural and Mathematical Sciences (BDM) Research Ethics Subcommittee (RESC) at King's College London (KCL) was acquired for this study on 17th July 2015 **(**LRS-14/15-1432**)**. Approval was also granted from the Research and Development department at the study hospital on 14th September 2015 and the study was allocated a Trust R&D registration number (RJ115/N256).

4.3.7. Piloting of data collection tools

Data collection tools, including the questionnaires, printed prescriptions, and the observation instrument were piloted with two nurses. Each of these nurses was also observed preparing two simulated tasks (one at the beginning and one at the end of the shift). The aim was to assess the clarity and validity of the questionnaires and observation instrument and to ensure that key details were collected clearly without any potential confusion. This pilot resulted in a minor amendment of one question in the pre-shift questionnaire to provide a new education level option, "PGDip 3 years".

The layout and order of some of the steps in the observation tool were slightly amended as per the routine sequence of preparation, to allow the observer to better follow the observation. The preparation and administration steps in the observation instrument were divided into four main sections: "before preparation", "preparation process", "administration process", and "labelling section". The pilot observations also allowed the observer to practice and develop his observation skills using the observation instrument.

4.3.8. Study participants

4.3.8.1. Inclusion and exclusion criteria

All nurses involved in IV preparation and administration on the study wards and working 12 hour night shift were eligible to participate. Nurses who were practicing in settings outside the study directorates and any nurses who did not administer IV doses were excluded.

4.3.8.2. Sampling

It was anticipated to select participants from different levels of grade/seniority (from Band 5 to Band 7) to represent the different levels of experience (Table 4.2). However, due to the nature of staffing level during the night shift, the majority of nurses participated in the study were band 5 with few band 6 nurses.

Table 4.2. Study settings and nurses sampling criteria (sample size=39)

Staff grade	ICU	Surgery wards	Acute Medicine wards
Band 5	5	5	5
Band 6	4	4	4
Band 7	4	4	4
Total	**13**	**13**	**13**

4.3.9. Participant identification and recruitment process

Details of participant identification and recruitment process are presented in Figure 4.1. All nurses in the wards involved in this study were informed about the study at least seven days before the study start, to increase awareness of the study and give nurses the opportunity to ask questions or obtain further information about the study. This was achieved using:

1 Information poster (Appendix 8) displayed in nurses' areas at all study directorates, to invite eligible nurses to participate.

2 An email with information about this study sent, via group emails for matrons and ward managers, to all hospital nurses to inform them about the study and to invite them to participate. The email provided information about the study aim, approvals obtained, eligibility criteria, details about participation, and instructions to complete and return the career/participant selection questionnaire.

Copies of the participant selection questionnaire (Appendix 9), and the participant information letter (Appendix 10) were provided alongside the poster and attached to the invitation email.

Nurses interested in participating in this study were asked to complete and send the selection questionnaire, by internal mail or by email, to the researcher, or leave it in the secure box provided on each study ward. Following review of the returned selection questionnaires, nurses selected to participate in the study were contacted to identify a convenient shift. They were also sent a personalised invitation letter together with copies of the participant information leaflet and consent form. Two copies of the consent form were provided; one for return to the research team and the other one for the participant to keep for reference. Any participant selected who did not subsequently respond to the invitation letter within seven days was excluded from the study and an alternative eligible nurse selected from the career questionnaire respondents was invited to participate.

4.3.10. Data collection and analysis

4.3.10.1. Data collection

All preparation tasks were performed in the ward's usual area for IV medication preparation in order to simulate the usual situation (i.e., at the bedside in ICUs and in the medication room in all other wards). Participants were asked to tell the observer when they would require an independent check of the simulated drug preparations. On the participation shift, before starting the observation, the researcher provided brief information about the study and the nature of the observation, and the participant had the opportunity to ask questions. The researcher also ensured that the participant had read and signed the written consent form before starting participation.

4.3.10.2. Data storage

All study data including all participants' questionnaires, observation tools, and consent forms, were stored in a locked filing cabinet in a locked office at, Kings College London. Each participant was given a reference number which was used throughout the study and stored separately from their contact details. Only the research team had access to this data.

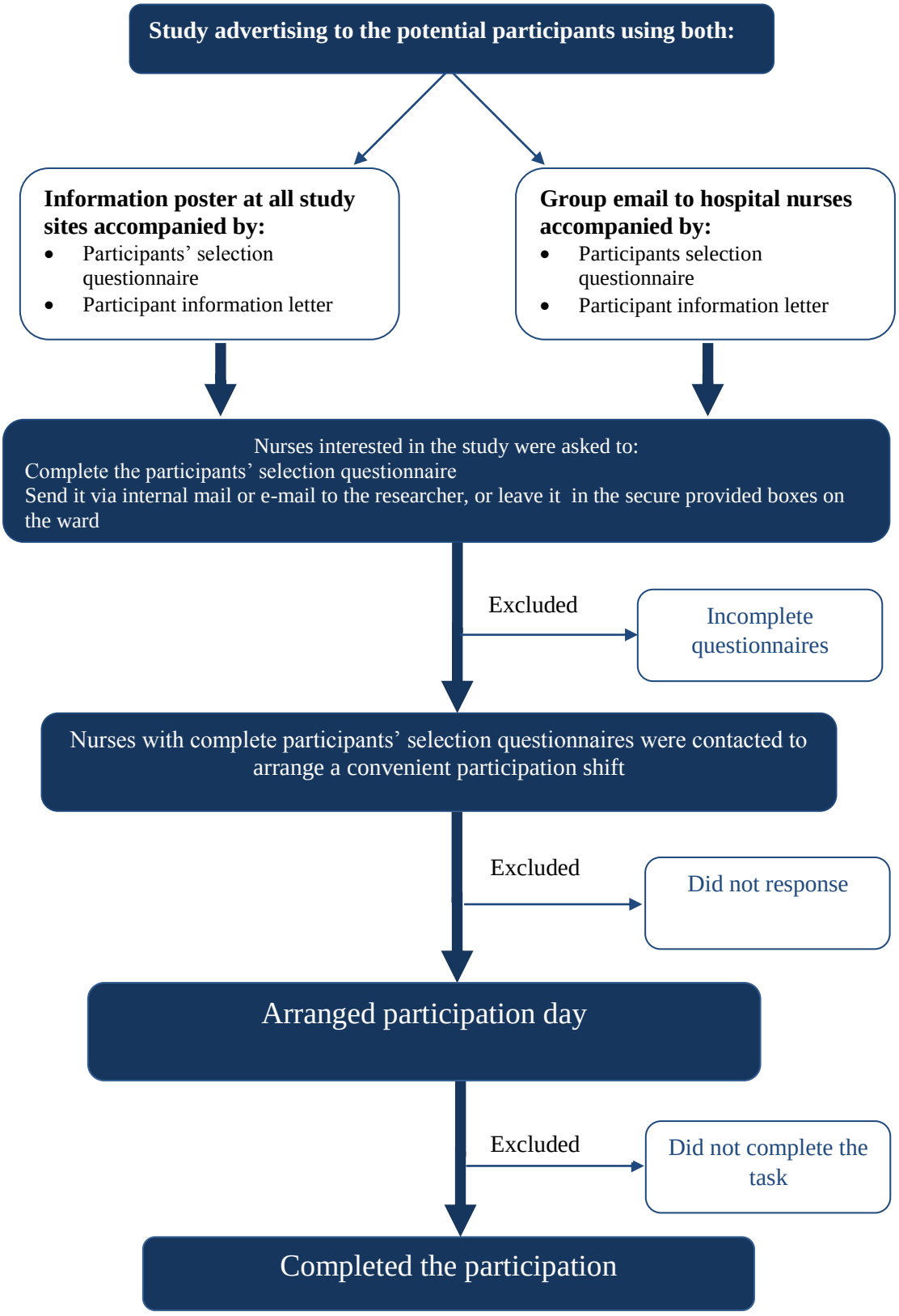

Figure 4.1. Flow diagram of participant identification and recruitment process

4.3.10.3. Data analysis

The opportunity for error was used as a unit of analysis to obtain the error rates for each observation period (Allan and Barker 1990). "Opportunities for error" were all doses that were prepared by participants. The error rate was obtained for each observation period. A research group meeting, which included the specialist IV pharmacist and a specialist in medication safety, was held at the end of all observations to discuss the data collected. All gathered information about observed errors, deviation from best practice, and any other information was discussed to finalise what were considered errors and what should be considered deviations from best practice based on the Trust IV guideline (Trust Drug and Therapeutics Committee 2015) and previous studies on IV medication errors (Taxis and Barber 2003, Cousins et al. 2005, Westbrook et al. 2011). The research group also classified the observed errors and deviations from best practice into the appropriate groups.

Participants' scores on the OFER scale items were calculated according to the specified criteria to quantify levels of acute fatigue, chronic fatigue, and intershift recovery among participants. Fatigue levels in OFER range between 0-100, with zero as the least fatigue and 100 as the most. Cronbach's alpha values were used to evaluate the internal reliability for OFER scale. Mean sleepiness scores were calculated for each time point. Paired two-sided t-tests were used to identify differences between acute and chronic fatigue states and whether any of these fatigue states occurred significantly higher than the others. Wilcoxon's signed-rank test and McNemar's test were used to evaluate the differences between sleepiness scores over time. Wilcoxon's signed-rank test was also used to examine the progression of "errors" and "deviation from best practice" at each time of observation (beginning and end of shift). Correlations among perceived acute fatigue, chronic fatigue, intershift recovery, and sleepiness scores were evaluated using nonparametric correlation analyses (Spearman's r_s). Multivariate analysis of variance (MANOVA) was used to examine the differences in fatigue levels of OFER measures across different demographic and work-related characteristics. McNemar's test was performed to examine the hypothesis that nurses reporting high levels of sleepiness were more likely to commit an error during the simulated drug preparation task. High level of sleepiness was defined as a score of seven or of greater on the Karolinska Sleepiness Scale. Both variables were treated as dichotomous variables i.e. sleepy/not sleep AND error/no error.

4.4. Results

4.4.1. Study sample

A total of 51 selection questionnaires were returned from the study directorates (medical = 19, surgery = 16, and ICU = 16). Of these, 45 were collected from the ward by the researcher, two were received via Trust internal mail, and four returned by email. Two of the received questionnaires were excluded because insufficient contact details were provided, resulting in 49 completed questionnaires from eligible participants. In total, 49 questionnaire respondents were contacted either by phone or email to arrange a day for their participation, of which three nurses did not respond to this communication, and seven could not complete their participation due to their increased workload on the observation day. A total of 39 nurses were finally observed resulting in 78 observations.

4.4.2. Demographic data of nurses

Details of participants' demographics and work characteristics can be found in Table 4.3 and Table 4.4. Similar number of nurses from medical (36%, n= 14) surgery (31%, n= 12) and ICUs (33%, n= 13) participated in the study. All participants reported working both day and night shifts. All participants indicated that they work 12 hours or more per shift and 85% (n=33) indicated that they worked over 40 hours per week at this nursing job. Years of experience as a registered nurse ranged from less than one year to 15 years. Participants' characteristics were similar between the two groups i.e., those who prepared the amphotericin at the beginning of the shift (n=19) (group A) and those who prepared the magnesium at the beginning of the shift (n=20) (Group B).

Table 4.3. Demographic characteristics of participants (n=39)

Participants' characters	Total (%)	Group A[1] (%)	Group B[2] (%)
Gender			
Male	2 (5)	0	2 (5)
Female	37 (95)	37 (95)	0
Age			
Under 25	12 (31)	6 (15)	6 (15)
25 – less than 35	22 (56)	12 (31)	10 (26)
35- less than 45	3 (8)	1 (3)	2 (5)
45- less than 55	1 (3)	0	1 (3)
55 - less than 65	1 (3)	1 (3)	0
Marital status			
Single	31 (80)	18 (46)	13 (33)
Separated	0	0	0
Married	7 (18)	2 (5)	5 (13)
Divorced	1 (3)	0	1 (3)
Number of dependents			
0	36 (92)	19 (49)	17 (44)
1 - 2	2 (5.1)	1 (3)	1 (3)
3 - 4	1 (2.6)	0	1 (3)
More than 4	0	0	0
Average hours of sleep per night			
Less than 5 hours	5 (13)	1 (3)	4 (10)
5 – 6 hours	14 (36)	10 (26)	5 (13)
7 - 8 hours	18 (46)	8 (21)	10 (26)
9 – 10 hours	1 (2.4)	1 (2.6)	0
Highest educational degree			
Nursing degree (3 years)	26 (69)	11 (28)	15 (36)
PGDip (2 years)	1 (3)	1 (3)	0
PGDip (3 years)	9 (23)	6 (15)	3 (8)
Master degree	3 (8)	2 (5)	1 (3)
PhD	0	0	0

[1] Nurses prepared amphotericin at the beginning of the shift
[2] Nurses prepared magnesium at the beginning of the shift

Table 4.4. Work related characteristics of participants (n=39)

Participants' characters	Total (%)	Group A[1] (%)	Group B[2] (%)
Work settings			
Medical	14 (36)	6 (15)	8 (21)
Surgical	12 (31)	8 (21)	4 (10)
ICU	13 (33)	6 (15)	7 (18)
Job title			
Deputy ward manager	1 (3	0	1 (3)
Staff nurse	38 (97)	20 (51)	18 (46)
Band			
5	36 (40)	20 (51)	16 (41)
6	3 (8)	0	3 (8)
Years as registered nurse			
Less than one year	5 (13)	2 (5.1)	3 (8)
1 – 5 years	30 (77)	18 (46)	12 (31)
>5 – 10 years	3 (8)	0	3 (8
>10 – 15 years	1 (3)	0	1 (3)
Usual shift length (hours)			
8 hours or less	0	0	0
9 to10 hours	0	0	0
11 to 12 hours	14 (36)	7 (18)	7 (18)
More than 12 hours	25 (64)	13 (33)	12 (31)
Total hours work per week			
Less than 20	0		
20-40	6 (15)	4 (10)	2 (5)
41 - 60	33 (85)	16 (41)	17 (44)
More than 60 hours	0	0	0
Additional responsibilities rather than direct patient care (on the observation shift)			
Yes	8 (21)	3 (8)	5 (13)
No	31 (80)	17 (44)	14 (36)
Number of patients the participant was responsible for during the observation shift			
1-2	15	8 (21)	7 (18)
3-4	7 (18)	2 (3)	5 (13)
5-6	9 (23)	5 (13)	4 (10)
7-8	8 (21)	4 (10)	4 (10)

[1] Nurses prepared amphotericin at the beginning of the shift
[2] Nurses prepared magnesium at the beginning of the shift

4.4.3. Fatigue levels

Data from OFER subscales evaluated the levels of acute and chronic fatigue, and intershift recovery among participants. Details of participants' perception of chronic fatigue, acute fatigue and intershift recovery can be found in Table 4.5. Cronbach's alpha values for all sub-scales ranged between 0.80 and 0.85. Paired t-tests showed that perceived acute fatigue (62.6%) at beginning of shift was significantly ($P < 0.001$) higher than chronic fatigue (49.6%). The mean scores of acute fatigue, chronic fatigue and intershift recovery were similar in the two groups of nurses (nurses who prepared amphotericin at the beginning and those who prepared magnesium at the beginning of the shift).

Table 4.5. Summary of fatigue sub-scales results

OFER subscale	No of items	Scores Range*	Mean			SD	Cronbach's Alpha
			Total	Group A[1]	Group B[2]		
Acute fatigue	5	30.0 - 96.7	63.4%	63.0%	63.8%	19.5	0.80
Chronic fatigue	5	20.0 - 86.7	49.6%	48.8%	50.5%	23.3	0.85
Inter-shift recovery	5	13.3 - 86.7	45.3%	47.9%	42.7%	20.5	0.85

[*] All subscales scores range from 0-100
[1] Nurses prepared amphotericin at the beginning of the shift.
[2] Nurses prepared magnesium at the beginning of the shift.

4.4.4. Sleepiness

Acute sleepiness of nurses was evaluated at three time points over the work shift. Table 4.6 presents the means of participants' sleepiness at the beginning of the shift, at 8 hours and at the end of the shift. Mean scores of sleepiness increased by the end of the shift, with mean scores starting at a shift of 2.85, increasing at 8 hours to 5.41, and then increasing further by the 12^{th} hour (the end of the shift) to 5.62. In general, sleepiness scores were significantly different over time ($p = 0.000$). Significant differences were identified between scores at the beginning of the shift and 8-hour scores ($p = 0.00$), and between scores at the beginning of the shift and at the end of the shift (at the 12^{th} hour) ($p = 0.00$). However, insignificant differences were found between 8-hour scores and 12-hour scores ($p = 0.80$).

Eleven participants had the opportunity to take a nap during the shift. The average length of naps taken was 52.7 minutes (range 30 - 80). The mean sleepiness scores at the end of the shift of the nap group decreased from 6.64 at 8 hours to 6.45 at the end of the shift, however this was not significant (p = 0.71). In addition, there were no significant differences in the mean sleepiness scores at the end of the shift between the nap group and other participants (Figure 4.2).

Table 4.6. Means for sleepiness scores over time for all groups

	Means of sleepiness scores			P*
	Beginning of shift	At 8 hours	End of shift (12h)	
All participants (n=39)	2.85	5.41	5.62	0.00*
Participants with nap (n=11)	2.55	6.64	6.45	0.00*
Participants without nap (n=28)	2.96	4.93	5.29	0.00*

*p-value for significance at α = 0.05

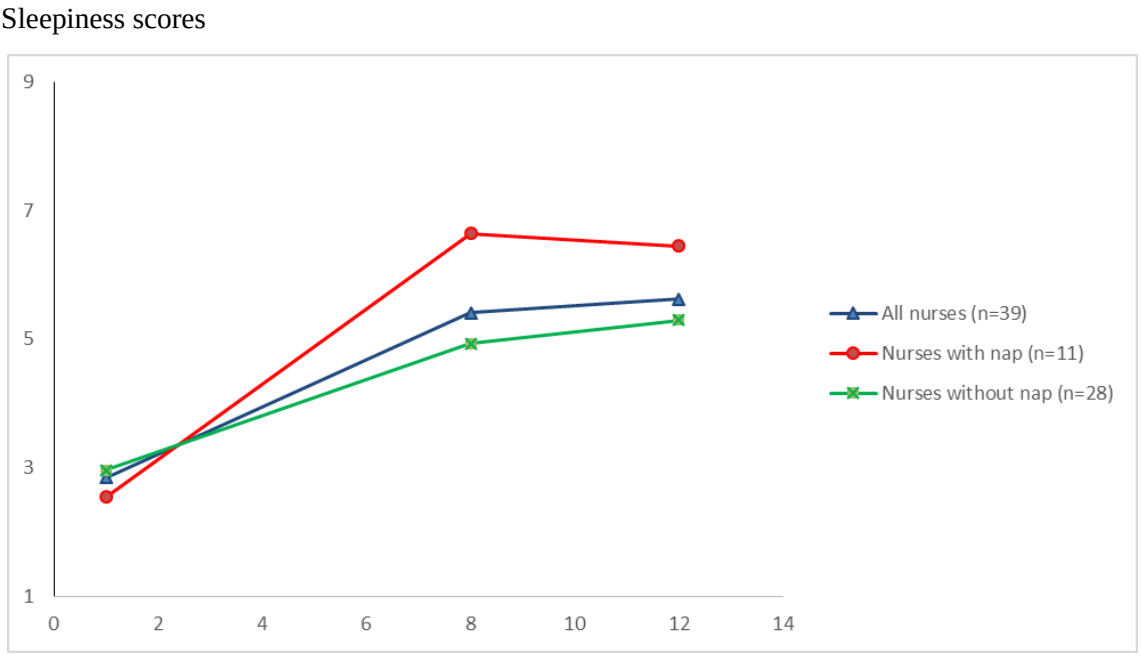

Figure 4.2. Sleepiness (KSS) into shift for nurses who took naps, nurses who did not take a nap and for all participants.

4.4.5. Differences in fatigue levels across demographic and work environment variables

Among demographic and work related variables, perceived fatigue levels of participants significantly differed between levels of age, and average hours of sleep. Both acute and chronic fatigue levels were significantly different across age as increased age was associated with increase in chronic fatigue levels ($p = 0.025$). For example, participants within the age group of 35-45 scored lower levels of chronic fatigue than those within the group of 45-55 and higher than those within the group 25-35. Acute fatigue also increased as average hours of sleep decreased ($p = 0.035$). Similarly, increased age of participants was associated with increased levels of acute fatigue. None of the other demographic or work related characteristics significantly associated with fatigue scores of participants.

4.4.6. Relationships between fatigue and sleepiness measures

Acute and chronic fatigue were significantly ($p = 0.00$) and positively correlated (Table 4.7). Both acute and chronic fatigue measures negatively and significantly ($p = 0.000$) correlated with intershift recovery. The only significant ($p = 0.000$) correlation between sleepiness scores was between sleepiness at 8 hours and at the end of the shift which was a positive relationship. When fatigue measures and sleepiness scores were considered, the only significant ($p < 0.05$) positive correlation was between acute fatigue and sleepiness at the end of shift.

Table 4.7. Correlations (r_s) among fatigue and sleepiness measures

	Chronic fatigue	Inter-shift recovery	Sleepiness at the beginning of the shift	Sleepiness at 8 hours	Sleepiness at 12 hours
Acute fatigue	0.65**	-0.63**	0.10	0.20	0.30*
Chronic fatigue		-0.62**	0.00	0.05	0.08
Inter-shift recovery			-0.12	-0.50**	-0.46**
Sleepiness 1[1]				0.06	0.05
Sleepiness 2 [2]					0.75**

**. Correlation is significant at the 0.01 level.
*. Correlation is significant at the 0.05 level.
[1] Sleepiness at the start of the shift
[2] Sleepiness at 8 hours

4.4.7. Observed errors and deviation from best practice

A summary of numbers of errors and deviations from best practice can be found in Table 4.8. A total of 13 (17%) tasks were associated with errors in both observation periods, 5 of which occurred at the beginning of the shift (13% of observations), compared to 8 errors at the end of the shift (21% of observations). Amphotericin was involved in 69% (9/13) of the observed errors while 31% (4/13) of errors occurred with magnesium.

Deviations from best practice for each preparation were also observed in both observation periods. At the beginning of the shift, a total of 163 deviations from best practice were observed in the 39 preparations, mean deviations per preparation of 4.18 compared to 247 (6.33) at the end of the shift. One or more deviation from best practice were observed in 97% (38/39) of nurses at the beginning of the shift and in 100% of observed nurses at the end of the shift. Wilcoxon signed-rank tests showed that within the two observation periods, the mean error rate at the end of the shift did not differ significantly from the mean error rate at the beginning of the shift ($p = 0.257$). However, a significant difference was found in the mean number of deviations between the two observation periods ($p = 0.000$).

Table 4.8. Numbers and means of observed errors and deviations from best practice

	Total (mean/observation) of errors and deviations				Differences in means	P*
	Beginning of shift	SD	End of shift	SD		
Errors	5 (0.13)	0.34	8 (0.21)	0.41	0.08	0.26
Deviations from practice	163 (4.18)	1.83	247 (6.33)	1.55	2.13	0.00*

*p-value for significance at $\alpha < 0.05$

4.4.8. Types of observed errors

Details of the types of observed errors in both observation periods are presented in Table 4.9. The five main types of errors identified were: incorrect dose preparation (n=8), setting incorrect infusion rate (n=2), inability to perform calculation (n=1), wrong dose identified (n=1), and using incorrect fluid (n=1). Incorrect dose preparation was the most common observed error, which occurred in 10% (n= 8/78) of all

observations and accounted for 62% (n= 8/13) of observed errors. Incorrect dose preparation occurred on 4 (10%) occasions during each observation period and was mainly associated with amphotericin (62%, n= 5/8) compared to magnesium (38%, n=3/8). Among all amphotericin preparations (n=39), incorrect dose preparation occurred in 13% (n= 5/39) compared to 8% (n= 3/39) of magnesium preparations. Table 4.10 shows the magnitude differences between the prepared dose and prescribed doses in errors which resulted in incorrect dose preparation for each medication and at both observation periods. All incorrect dose preparations resulted in an excessive dose. In all incorrectly prepared doses of magnesium, nurses prepared twice the prescribed dose. However, with amphotericin, the differences from the prescribed doses ranged from +1.3%% to +3.5%.

Incorrect infusion rate occurred in one observation at the beginning of the shift (amphotericin) and in one observation at the end of the shift (magnesium). Wrong dose identified (amphotericin), inability to perform calculation (amphotericin), and using an incorrect diluent (amphotericin) each occurred on one occasion and all of them occurred at the end of the shift (Table 4.9).

Table 4.9. Types of observed errors at both the beginning and end of the shift (n=13)

Error type	**No (%) of observed preparations with errors**				
	Beginning of shift	Medication	End of shift	Medication	Total
Wrong dose identified	0		1 (3)	Amphotericin	1
Inability to perform calculation	0		1 (3)	Amphotericin	1
Incorrect dose preparation					
Incorrect volume added to the bag	4 (10)	Magnesium (x2) Amphotericin (x2)	2 (5)	Magnesium Amphotericin	6
Incorrect reconstitution	0		2 (5)	Amphotericin (x2)	2
Incorrect diluent used	0		1 (3)	Amphotericin	1
Incorrect infusion rate	1 (3)	Amphotericin	1 (3)	Magnesium	2
Total (%)	**5 (13)**		**8 (21)**		**13 (33%)**

Table 4.10. Incorrect dose preparations including magnitude of dose error

Medication involved	Total	% less or more than prescribed dose	
		Beginning of shift	End of shift
Magnesium	3	+ 100% + 100%	+ 100%
Amphotericin	5	+ 3.5% + 1.3%	+ 3.5% + 3.5% + 3.5% -65.5%

A total of 10 nurses made at least one error, with three nurses making errors both at the beginning and end of shift. In ICU, 15% (n= 2/13) of participants made at least one error compared to 33% (n= 4/12) on surgical and 36% (n= 5/14) on medical wards.

4.4.9. Types of deviation from practice

The observed deviations from best practice were classified into four main types and 14 subtypes. Table 4.11 provides details of these types and subtypes together with their occurrence at the two observation periods. The four main classes were deviation from aseptic technique, failure to conduct the required checking, manipulation and assessment of product integrity, and deviations associated with setting up the pump. Within the observed deviations from best practice, the compliance with seven out of fourteen best practice steps at the end of the shift was significantly lower than the compliance at the beginning of the shift (Table 4.11).

When adjusting the volume in the pump, nurses usually adjusted the total volume (i.e. the total volume of the bag in addition to the volume of drug added). During some tasks at both observation periods, the participants did not take into consideration the drug volume when setting the pump volume. The drug volume was equal to 5mL for magnesium and 34.8 for amphotericin. This deviation occurred with both medications, however most deviations occurred with magnesium (n=5).

Table 4.11. Types of observed deviations from best practice at each time point

	Deviations from best practice	Number (%) of preparations not complying		P*
		Beginning of shift	End of shift	
Aseptic technique				
1	Wash hands	15 (38)	26 (67)	0.00*
2	Wear gloves	1 (3)	1 (3)	1.00
3	Disinfect the vial	12 (33)	18 (46)	.031*
Checking processes				
4	Expiry date	1 (3)	2 (5.1)	0.32
5	Request independent check	17 (44)	27 (69)	0.00*
6	Prepared medicine against prescription	34 (87)	38 (97)	0.04*
7	Retain vials/ampoules for checking purposes	0	0	1.00
Manipulation and assessment of product integrity				
8	Assess product integrity and that there is no damage to containers or vials	7 (18)	24 (62)	0.00*
9	Use a filter and change the needle	22 (56)	29 (74)	0.31
10	Shake the vial after adding the solvent	2 (5)	4 (10)	0.16
11	Mix after adding the drug	20 (51)	34 (87)	0.00*
12	Assess appearance of the final product	24 (61)	38 (97)	0.00*
Setting up the pump				
13	Setting up the correct volume	7 (18)	5 (13)	0.45
14	Setting up the correct time	1 (3)	1 (3)	1.00
Total of deviations		**163**	**247**	**0.00***

*p-value for significance at $\alpha < 0.05$

4.4.10. Labeling errors

The infusion label consists of 12 fields. A total of 36% (n= 14) of labels at the beginning of the shift were complete and correct compared to 28% (n= 11) of labels at the end of the shift. A summary of the errors observed on infusion labels is provided in Table 4.12. Details of drug name and amount of drug, were completed and correct in all labels at both observation times. Other details such as diluent used, total volume, preparation date and time, patient details (name and hospital number), and route were also completed and correct in most labels. Documentation of infusion expiry date and time were the most likely details to be either incomplete or incorrect. Expiry date and time were incomplete in 46% (n= 18) of labels and incorrect in an additional 18% (n= 7) at the beginning of the shift compared with 51% (n= 20) incomplete and 15% (n= 6)

incorrect labels at the end of the shift. In all cases of documentation of wrong expiry date and time, participants wrote the expiry date of the original medication. However, among labeling errors, no significant differences were observed between the two observation periods.

Table 4.12. Summary of complete correct, complete and incorrect and incomplete labels

Information (label fields)	No (%) of complete and correct labels		No (%) of incomplete labels		No (%) of complete but incorrect labels	
	Beginning of shift	End of shift	Beginning of shift	End of shift	Beginning of shift	End of shift
Drug	39 (100)	39 (100)	0	0	0	0
Amount of drug	39 (100)	39 (100)	0	0	0	0
Diluent	37 (95)	39 (100)	1 (3)	0	1 (3)	0
Total volume	33 (87)	32 (82)	0	0	6 (15)	7 (18)
Route	38 (97)	37 (95)	1 (3)	2 (5)	0	0
Preparation date and time	33 (95)	26 (67)	6 (15)	13 (33)	0	0
Expiry date and time	14 (36)	13 (33)	18 (46)	20 (51)	7 (18)	6 (15)
Patient name	33 (87)	29 (74)	6 (15)	10 (26)	0	0
Hospital number	35 (90)	35 (90)	4 (10)	4 (10)	0	0
Ward	36 (92)	36 (92)	3 (8)	3 (8)	0	0
Signature	38 (97)	38 (97)	1 (3)	1 (3)	---	---

4.4.11. Preparation time

The time needed to complete preparation and set the pump is shown in Table 4.13. The mean preparation time for magnesium was 11.9 minutes (range 6 - 21) at the beginning of the shift and 12.1 minutes (range 7 - 22) at the end of the shift. For amphotericin, the mean preparation time was 22.4 minutes (range 16 - 29) at the beginning of the shift and 22.9 minutes (range 15 - 38) at the end of the shift. No significant differences were found between the two observation times for both medications.

Table 4.13. Means of preparation time in minutes for each drug

Medication	Beginning of shift	SD	End of shift	SD	P
Magnesium	11.9 min (n=20)	5.6	12.1min (n=19)	4.2	0.55
Amphotericin	22.4 min (n=19)	3.9	22.9 min (n=20)	5.5	0.72
Mean	**17.0 min (n=39)**	**7.2**	**17.7 min (n=39)**	**7.2**	**0.72**

4.4.12. Relationship between sleepiness and errors and best practice deviations

McNemar's test showed a significant ($p = 0.002$) association between being sleepy and making errors at the end of the shift. However, this association was not significant at the beginning of the shift. There was no significant relationship between sleepiness scores and number of deviations from best practice either at the beginning of the shift ($p = 0.16$) or the end of the shift ($p = 0.25$). Furthermore, no significant relationship was found between acute or chronic fatigue and the observed errors ($p = 0.45$) or deviations ($p = 0.45$) at any of the observation periods.

4.5. Discussion

4.5.1. Observed errors and deviations from the best practice

Errors were observed in 13% of observations at the beginning of the shift and in 21% of observations during the end of the shift, yielding an increase of around 8%. The baseline error rate was higher than the assumption used in the sample size calculation (3%), whilst the change was less than the assumption made when the sample size was calculated (40%). Of all simulated preparations observed during this study, 10% were associated with incorrect dose preparation, which was the most frequent type of error. Errors of incorrect dose preparation represented the majority of observed errors (62%). These errors occurred equally in each observation period and were more frequent with amphotericin than magnesium. The steps in which the dose preparation errors occurred varied. In six cases involving both magnesium and amphotericin, the errors occurred during the step of withdrawing the drug from the ampoule or vial into the infusion bag. Taxis and Barber (2003) determined the incidence and clinical importance of errors in the preparation and administration of IV drugs and the stages of the process in which

errors occur in teaching and non-teaching hospitals in the UK. The study found that the most common types of preparation errors were errors in using diluents (8%) and wrong dose preparation (3%). In the current study, in cases of magnesium where the participant drew up the whole content of the ampoule, resulting in a double dose, the observer was not able to observe the participant performing the calculations. Therefore it was not possible to determine whether the incorrect volume withdrawn was because of miscalculating the dose or misreading the prescription. The incorrect dose of magnesium prepared, however, is considered a usual dose in some areas such as in ICUs and therefore, nurses' lapses in checking the dose in the prescription could be a potential cause. In cases that involved amphotericin, although correct calculations and reconstitutions were performed, an incorrect volume was withdrawn and added into the bag when nurses withdrew the whole reconstituted volume instead of the calculated volume. This also could be due to nurses' lapses in double checking the calculated dose before adding the drug into the infusion bag.

The step of reconstitution was associated with another two errors and resulted in incorrect dose preparation. These errors occurred when the participants confused the reconstitution volume of the diluent and the volume that should have been withdrawn and added into the infusion bag. In both cases, the participant used the volume that should be withdrawn to reconstitute the drug, which led to adding an excessive dose into the infusion bag. The study of Taxis and Barber (2003) also identified that the most preparation errors were associated with multiple step preparations (14%, n= 50/345), such as drugs that required reconstitution with a solvent and addition of a diluent. A typical error was preparing the wrong dose; all three severe errors observed in this Taxis and Barber's study occurred at this stage. McDowell et al. (2010) showed that the reconstitution stage in IV preparation was the most error-prone step and that eliminating this step by using ready-to-use infusions reduced the probability of making an error in IV preparation and administration from 0.73 to 0.17. In another study, using the wrong volume of solvent or diluent to prepare an IV medication was the second most common (33%, n= 121/363) type of errors observed (Westbrook et al. 2011).

An incorrect infusion rate occurred on one occasion in each observation period with both medications. This rate of incorrect infusion rate error is lower than reported in other studies: 27% (Wirtz et al. 2003); 48% (Cousins et al. 2005); and 47% (Westbrook

et al. 2011). However, incorrect infusion rate was the second common type of errors observed after incorrect dose preparation. In most IV errors studies, incorrect administration rate was observed as one of the three most common types of errors (Wirtz et al. 2003, Cousins et al. 2005, Westbrook et al. 2011).

Almost all preparations in both observation periods were associated with at least one deviation from the best practice. High nurses' compliance with some steps e.g. wearing gloves, checking the expiry date, and shaking the vial after adding the solvent was observed in both observation periods. No significant differences in nurses' compliance with these steps were found between the beginning and end of a shift. The compliance by nurses to these steps in the current study was higher than the few studies which assessed the prevalence of nurses' deviations from best practice while preparing and administering IV doses. The observational study of Ong and Subasyini (2013) showed 26% of nurses comply to wearing gloves when preparing IV doses while, Gill et al. (2012) showed that 83% of nurses check the name and expiry of IV medication before administration.

In contrast, low compliance with checking processes was observed in almost all preparations during both observation periods, which may be considered as a usual practice by nurses. Previous studies found that inappropriate checking is a common practice by nurses which may considered a significant contributor to errors particularly with IV doses (Armitage and Knapman 2003, Westbrook et al. 2011, Gill et al. 2012, Keers et al. 2013). A study on errors in IV administration by Westbrook et al. (2011) revealed that steps of reading medication labels, using aseptic technique, double checking, and documenting medication administration were the most violated procedures by nurses. The systematic review of McDowell et al. (2010) found that appropriate checking during IV dose preparation and administration reduced the error rate from 0.73 to 0.22. Variation in compliance by nurses with the checking process during medication preparation and administration was found in previous studies, ranging from 50% (Westbrook et al. 2011) to 89.5% (Gill et al. 2012). In the current study, lower compliance with double checking was observed at the end of the shift (31%) than in previous studies although higher compliance was seen at the beginning of the shift (56%). This difference which was found to be significant might be linked to the impact of the shift length and nurses' sleepiness at the end of the shift.

The nurses' compliance to five steps became increasingly reduced over the course of the shift compared to the start of the shift. These were hand washing prior to the start of preparation, disinfecting the vial before use, assessing product integrity, mixing the solution after adding the drug, and assessing the appearance of the final product. Specifically nurses' compliance with washing hands prior to the start of the preparation significantly decreased over the shift time, even though the Trust policy emphasised the importance of washing hands before starting preparation as aseptic requirements for infection control (Trust Drug and Therapeutics Committee 2015). Nurses' non-compliance rate with hand washing requirements (38% - 67%) in the current study was higher compared to Ong and Subasyini (2013) and Westbrook et al. (2011) (26% and 10% respectively). Absent or inappropriate use of a filter needle was observed in a high percentage of preparations in both observation periods. A high proportion of nurses used the filter without changing the needle. Poor compliance with filter use and frequent inappropriate use in both observation periods suggests that this is a routine deviation acted upon by a large proportion of nurses. However, none of IV error studies reported data about the compliance and appropriateness of using filter needle among nurses.

Overall, the mean number of deviations per task significantly increased at the end from the beginning of the shift. This indicates that nurses were less compliant with best practice standards when preparing and administering IVs at the end of their 12-hour shift, compared to their performance at the beginning of the shift.

4.5.2. Fatigue levels

In the OFER scale, fatigue scores range from 0-100 where a higher score indicates a higher level of fatigue. Winwood et al. (2006) indicated that scores of 25-50 reflect low/moderate fatigue and 50-75 reflect moderate/high fatigue. Cronbach's alpha values in this study (0.8-0.85) indicated that all fatigue sub-scales had acceptable reliability (Winwood et al. 2005). In this study, nurses showed that they perceived more acute fatigue (moderate/high) than chronic fatigue, although the chronic fatigue levels, which averaged ~50%, would be considered moderate. Fatigue levels in the current study are comparable to levels reported among nurses in the US and Australia using the same scale (Winwood et al. 2005, Winwood et al. 2006, Barker and Nussbaum 2011). Acute fatigue has been described by Barker and Nussbaum (2011, p1372) as:

"*a temporary state which is commonly experienced by healthy people during the course of work or daily life activities*" .

The increased levels of acute fatigue scored by nurses in the current study were also consistent with previous research that showed that acute fatigue is more common than chronic fatigue among workers, especially those who work irregular shifts (Winwood et al. 2006, Barker and Nussbaum 2011). Acute fatigue was demonstrated to be a result of work-related demand that exhausts energy (Winwood et al. 2005). However, chronic fatigue was also identified as a common result among workers who experienced increased acute fatigue levels with insufficient recovery between shifts (Winwood et al. 2005).

The current study identified a significant negative correlation between inter-shift recovery and both fatigue statuses (acute and chronic). The fact that nurses in the current study described moderate to high levels of acute fatigue (62.6%) and low levels of recovery between shifts (45.0%) indicates that nurses may did not experience sufficient recovery from acute (end of shift) fatigue between shifts, which may exacerbate chronic fatigue levels. Furthermore, acute and chronic fatigue in this study and other studies (Winwood et al. 2006, Barker and Nussbaum 2011) were found to be significantly correlated, which indicate that fatigue components may overlap and that the transition of acute fatigue to chronic fatigue therefore is expected (Winwood et al. 2006). Therefore, nurses may need longer time between consecutive long shifts to recover from acute fatigue. It is important to consider the measurements of chronic fatigue levels as well as inter-shift recovery when evaluating the efficiency of extended work shifts for nurses (Barker and Nussbaum 2011). In addition, the maximum number of consecutive shifts nurses perform as well as the rest time nurses receive between shifts should be considered when designing shift schedules.

Previous research in occupational fatigue (Trinkoff et al. 2006, Winwood et al. 2006) also found that increased prevalence of long shifts was associated with moderate levels of chronic fatigue among workers. This study could not determine the relationship between the type of shift and perceived fatigue as all participants were working long irregular shifts. However, the moderate levels (~50%) of chronic fatigue found in the

current study might be resulted from the length of the shifts they work and insufficient rest time between shifts

Although acute fatigue is considered more common among workers, chronic fatigue was found to have a more considerable effect on workers' health and performance (Winwood et al. 2005). Barker and Nussbaum (2011) conducted a study about the relationship between different fatigue dimensions and performance among nurses. This study, which reported comparable fatigue levels to the current study (moderate/high acute fatigue with moderate chronic fatigue), found that both fatigue status have comparable negative correlation with nurses' performance, as measured using Nursing Performance Instrument (NPI) for nurses' mental and physical performance. In particular, chronic fatigue had a stronger correlation with some nurses' malpractice, such as taking shortcuts, which may provide an explanation for the increased prevalence of non-compliance of nurses in the current study to the Trust standards for IV preparation and administration. Therefore, when evaluating long shifts in the nursing practice, both chronic fatigue and inter-shift recovery measures should be considered to avoid any potential impact of fatigue on nurses performance and medication safety.

4.5.3. Sleepiness levels

This study showed a significant progression in nurses' sleepiness across the shift. The mean KSS scores increased from 2.85 at the beginning of the shift to 5.62 at the 12th hour, with 15 nurses reporting a high level of sleepiness at the end of the shift defined by Geiger-Brown et al. (2012) as the upper one-third of the scale. This is much higher than the sleepiness reported in another US study using KSS when the means of sleepiness scores across the shift started from 2.8 to 3.9 at the 12th hour (Geiger-Brown et al. 2012). In addition to increased sleepiness during the shift, 49% of participants in the current study also reported short sleep duration between shifts with an average of less than six hours. This is expected, given that 95% of our sample were aged less than 45 years, wherein increased sleepiness often results from sleep deficiency (Duffy et al. 2009). In addition, this is consistent with previous studies which showed that short sleep duration a between shifts is common among healthcare staff working shift schedules (Luckhaupt et al. 2010), and in particular in nurses (Geiger-Brown and Trinkoff 2010, Geiger-Brown et al. 2012).

The risk of nurses' insufficient and poor sleep on patient safety incidents has been demonstrated by several studies. An Australian study among hospital nurses using logbooks found that the risk of medical errors increased when nurses reported shorter sleep duration (Dorrian et al. 2008). In another study, Dorrian et al. (2006) identified that reduced sleep among nurses may be associated with increased likelihood of making errors and also decreased likelihood of intercepting errors. Both failures are important for nurses, given that nurses are a principal interceptors of errors detecting about 50% of prescribing errors and around 30% of transcribing and dispensing errors (Leape et al. 1995). Sleep deprivation has also been found to affect other healthcare professional. Baldwin Jr and Daugherty (2004) revealed that around 20% of 3,604 doctors who responded to a survey about their experience reported an average sleep per night of five hours or fewer, with 66% reporting an average of six hours or fewer. This survey showed that doctors with five or less hours of sleep per night reported more accidents or injuries, and more medical errors compared to those averaging more than five hours sleep per night.

When considering the effect of long hour shifts on observed errors and deviation from best practice, observed errors did not significantly differ between the two observation periods. However, nurses' compliance with best practice at the end of the shift significantly decreased compared to the beginning of the shift. The findings of this study also showed a significant progression of nurses' sleepiness over time (between the beginning of the shift and at 8 hours and between the beginning of the shift and at 12 hours). A significant association was identified between reporting high levels of sleepiness at the end of the shift and committing an error. This indicates that when nurses were sleepier at the end of the 12 hour shift, they were more likely to make an error. The current study observed nurses performing simulated tasks at the beginning and end of the shift and measured nurses' stated sleepiness during the shift rather than self-reported errors identified in previous studies. Therefore, the impact of nurses' sleepiness on IV medication safety at the end of night shift should be considered when assigning tasks to night shift nurses such as preparation and administration of morning IV medications.

4.5.4. Study limitations

This study had some limitations. When it was designed, it was anticipated that the observations would be performed before and after the shift; however, due to the length of nurses' shifts, it was difficult for them to arrive before and stay after the night shift. Therefore, all observations were conducted within the first and last hours of the shifts to ensure adherence to the study objectives. Nurses were aware that the IV preparation task was a simulation and therefore none of the prepared doses in the study were intended to be administered to patients. This may have affected nurses' performance as they may not have behaved in the same way as in real situations. However, before the observation began, clear instructions were given to the nurses, and they were asked to consider the task as a real preparation and to undertake the task on that basis.

When the study was designed, the initial plan was to recruit nurses from different grades (Bands 5 to 7). However, the nature of night-shift staffing levels only allowed recruitment of Band 5 nurses and a few (n=3) Band 6 nurses. Nonetheless, the sample size reflected the reality of night-shift nursing in the study trust. Furthermore, the recruited nurses represented all study settings, and a similar number of participants were recruited from study wards.

Another limitation of the study was the small sample size and the limited number of observations possible, which resulted in a small number of errors. However, this was an initial study and given the lack of published literature on the relationship between errors and sleepiness, certain assumptions had to be made. Errors at the start of shift (13%) were higher than the assumption in sample size calculations, whilst errors at shift end were fewer (21%) than the assumption (40%) used when the sample size was calculated. However, the sample size was sufficient to confirm the association between nurses' sleepiness and occurrence of errors.

Although the two simulated tasks used for this study were developed in collaboration with a specialist pharmacist in injectable medicines safety, it was not possible to validate the equivalency of these preparations by the nurses because of time constraints. Finally, the study Trust has two sites, however due to logistical issues with only one researcher collecting observation data, participants were recruited from only one site. ICU staff rotate between sites, and both sites have similar work environments, therefore

it is possible that results are applicable to the Trust as a whole rather than the specific site.

4.6. Conclusion

This study identified the effect of nurses' fatigue and sleepiness during long shifts on IV medication preparation and administration errors using an observational technique and simulated IV preparations. The study identified moderate to high levels of fatigue among nurses. High levels of sleepiness were also identified with a significant progression into shift hours. Furthermore, a significant association was identified between being sleepy and making error at the end of the shift. The current study also showed a significant decrease in nurses' compliance with best practice at the end of the shift compared with the beginning of the shift. Nurse managers should consider the impact of nurses' fatigue and sleepiness on IV medication safety at the end of night shift when assigning morning IV doses to night shift nurses. In addition, the findings of this study can be used to identify IV preparation and administration processes in which nurses need more training. This would allow education to be developed on the steps that nurses should follow when preparing and administering IVs.

Chapter 5. General Discussion

5.1. Overview

This thesis investigated the safety of medication administration in hospitals, starting with a description of issues related to patient safety, iatrogenic injury, and the resulting consequences. Different policies and dedicated quality and safety organisations were developed by governments and healthcare systems to address healthcare quality issues and improve patient safety. The main role of organisations like the US AHRQ, the NCC MERP, UK NPSA, and WHO Patient Safety Programme is to monitor and analyse incidents, and then develop strategies to minimise them. For example, the UK NPSA was established to lead the government's agenda for improving healthcare quality and patient safety by launching a national reporting system for patient safety incidents and publishing lessons learned from analysing these incidents (DoH, 2001b, NPSA, 2004). Since 2012, the patient safety key functions of the NPSA have transferred to the NHS Commissioning Board Special Health Authority (the Board Authority) to ensure developing patient safety improvement and address patient safety issues (National Patient Safety Agency 2015). The introduction of this thesis also discussed the models of clinical incident causation analysis, including human contribution theory by Reason (1990) and Vincent et al's (1998) framework for factors influencing accidents in clinical practice (section 1.3).

As the most common treatment given to patients, medications are considered a main source for PSIs (Vogenberg and Benjamin 2011, Cousins et al. 2012, National Patient Safety Agency 2013). However, medication incidents were found to be highly preventable (Bates et al. 1995, Wilson et al. 1995, Barker et al. 2002, Runciman et al. 2003). Therefore, extensive research has been conducted internationally to investigate safety incidents associated with medication use in healthcare settings (Leape et al. 1991, Wilson et al. 1995, Vincent et al. 2001, Barker et al. 2002, Taxis and Barber 2004, James et al. 2008, Morimoto et al. 2010, Poon et al. 2010, Cousins et al. 2012, Rodriguez-Gonzalez et al. 2012)

Many studies have found that medication-related incidents were more common during the administration stage than during other stages of the MUP (Ashcroft and Cooke 2006, National Patient Safety Agency 2007, Alrwisan et al. 2011). Furthermore, in the UK, most medication-related incidents which resulted in patient harm or death related to administration (National Patient Safety Agency 2007). This suggests that efforts are

required to improve the safety of administration of medication in hospitals. Understanding how and why errors occur is fundamental to achieving this aim (Keers et al. 2013).

In focussing on the problems of MAIs in the hospital setting, this thesis first investigated the reported administration-related incidents in one large NHS acute teaching Trust over one year. This study used the number of reported MAIs compared to the total number OBD as a unit of comparison to accurately identify clinical directorates where reporting rate was higher. Following this retrospective study, a semi-structured interview-based qualitative study was conducted to explore the views and perspective of nurses and midwives about the common causes and contributing factors leading to administration incidents in hospitals. Finally, this thesis used direct observation to investigate the impact of nurses' sleepiness and fatigue, during long night shifts, on errors and deviations from best practice when preparing IV doses and setting up an infusion pump for two simulated tasks.

5.2. Evaluating safety incidents during medication administration

Chapter 2 of this thesis analysed the reported medication related incidents to the electronic incident reporting system in one NHS teaching trust. One of the advantages of incident reporting is that it provides a broad set of data from different locations over an extended period of time, which allows researchers to more easily compare incidents between different settings or in the same setting over time, and monitor harmful incidents (Allan and Barker 1990, Barker et al. 2002). Therefore, this analysis weighted the number of reported MAIs by the total number of OBDs. Incident reports also seek to learn from incidents, and identify potential solutions (Thomas et al. 2002, Thomas and Petersen 2003, Shojania 2010).

Most MI studies using voluntary incident reports have reported the overall number of reported incidents and have not used any denominator such as bed occupancy to compare the number of reports between different settings (Ashcroft and Cooke 2006, Alrwisan et al. 2011, Cousins et al. 2012). High patient occupancy in some clinical areas resulting in a higher number of incident reports may be assumed to have higher medication risk, while areas with fewer beds and incidents reports may be assumed to

have lower medication risk. The result of this difference in unadjusted reporting rates means that some locations may be less likely to be investigated and therefore miss the opportunity to implement preventive strategies. Thus, this study weighted reported incidents by OBDs in each clinical area to correct for areas with high occupancy and generated incident reporting rates for each clinical area. As shown in Table 2.8, this was more useful in comparing the incident reporting rate between different clinical areas than just providing the absolute number of incidents.

In the current study, when the number of reported MAIs compared to the total number of OBDs was considered, some clinical areas which reported fewer incidents were found to have higher reporting rate of MAIs than other areas with more patients. For example, based only on the number of reports, 'Children's Services' had the highest number of reported incidents and almost double the number of incidents reported in 'Perioperative, Critical Care and Pain'. However, as shown in Table 2.8, the rate of reported incidents to the total number of OBDs in the 'Perioperative, Critical Care and Pain' directorate was much higher than all other areas. Therefore, this study demonstrated that some clinical areas associated with a high number of reported incidents do not necessarily reflect the increased rate of reporting in these areas. Conversely, the increased reporting rate associated with clinical areas with low bed occupancy may not be accurately identified by incident reports analysis.

Comparison between studies may be limited because of the different hospital settings; definitions; and prescribing and administration systems (Allan and Barker 1990). However the results of this study were consistent with previous UK studies (Hicks et al. 2004, Ashcroft and Cooke 2006, Alrwisan et al. 2011) in that the proportion of reported incidents during the administration stage was higher than other stages of the MUP. Almost half of the reported incidents in these studies were administration-related. The incident types in the current study were also comparable to other UK and international studies which also identified omissions, delays, and administering the wrong dose or drug to be the most common types of administration incidents (Ashcroft and Cooke 2006, Franklin et al. 2007, Poon et al. 2010, Cousins et al. 2012).

5.3. Causes and contributing factors of medication administration incidents

The increased proportion of reported incidents during the medication administration stage led the researcher to propose a semi-structured interview-based study to investigate nurses' and midwives' views about the causes and contributing factors of MAIs (Chapter 3). Most studies which investigated the causes and contributing factors of errors have relied on self-reported questionnaires/surveys, medication error reports, or direct observation, and focused on the causes behind the documented, reported, or observed errors. Only one study has been conducted in the UK and considered the perception and views of nurses on causes and contributing factors of MAEs using qualitative interviews (Hand and Barber 2000). In addition, several recent changes had been introduced in the study trust, e.g. long shifts, automated dispensing cupboards on wards, an electronic prescribing and medication administration system, and increased recruitment of new junior nurses, especially in critical care units. These changes may have had an impact on medication administration safety in the study hospital, particularly given UK healthcare's ongoing move towards greater use of electronic medication systems.

Interviews with healthcare professionals have been used in previous medication safety research to investigate the causes and contributing factors of prescribing and dispensing errors (Dean et al. 2002) as semi-structured interviews enable the interviewer to explore further details about the topic (Ritchie and Lewis, 2003). This study yielded seven main themes, with 46 codes and sub-codes emerged from the interview data. The themes identified were environmental, task, patient, team, management, personal or individual factors, and factors associated with IV doses.

Factors of increased workload, low staffing levels, frequent interruptions and distractions, fatigue and sleepiness associated with long working hours, inadequate nurse training, inappropriate checking and lack of communication or miscommunication between nurses or with doctors were mentioned by nurses and midwives as the most common factors contributing to administration incidents. Most of these factors have been previously reported as issues affecting the focus of nurses and contributing to administration incidents in qualitative and quantitative studies (Pape 2001, Pape et al.

2005, Tang et al. 2007, Biron et al. 2009, Brady et al. 2009, Westbrook et al. 2010, Keers et al. 2013).

Consistent with the interviews study, increased workload was also considered by several studies as one of the most common predictors of MAEs and related to inadequate staff or inappropriate staffing level (Tang et al. 2007, Jones and Treiber 2010, Gill et al. 2012, Keers et al. 2013). Appropriate staffing level and skill mix has been also identified as a factor affecting the safety of medication administration (Tissot et al. 2003, Frith et al. 2012). Increased workload was also linked to patient's acuity the number of patients' medications by some interviewees. In this thesis, interviewees suggested that incidents commonly associated with increased workload were omissions and delays. These were the most common administration incident reported in the incident report study (Chapter 2). Interviewees reported that such incidents were more likely to occur during busy times when medication tasks were performed under time pressure. In addition, nurses and midwives in the interviews reported that increased workload and short staffing are also common causes of non-compliance with the checking process, specifically with double checking which was reported as one of the common causes and contribution factors of MAEs (Gill et al. 2012, Keers et al. 2013).

Interruption and distraction was commonly reported by nurses and midwives as a contributing factor beside increased workload and long shifts. A number of studies have investigated the rate and impact of interruption on MAEs. Furthermore, Dieckmann and colleagues (2006) demonstrated that human prospective memory, which enables remembering intended activities and supports correctly resuming actions, can be impaired by interruptions and distractions. Studies have also examined different interventions employed to manage interruptions during medication administration. However, no evidence was identified to support the effectiveness of these interventions in reducing interruptions to nurses (Raban and Westbrook 2014). Moreover, this systematic review concluded that in order to provide evidence of effectiveness of these any intervention, further research require a controlled randomised or cluster randomised studies across multiple sites (Raban and Westbrook (2014).

One of the contributing factors to MAIs which were commonly reported in nurses' interviews in the current study was long shifts (12-hour shifts) and night shifts. In the

study hospital, morning doses of IV medications are commonly administered by the night shift nurses at the end of their shift. This is when sleepiness and fatigue may be anticipated to be high, as previous studies have found that night shifts are associated with poor sleep and consequently increased levels of fatigue Ruggiero (2003), (Kunert et al. 2007, Geiger-Brown et al. 2012). Furthermore, Geiger-Brown et al. (2012) found nurses' sleepiness increased toward the end of 12-hour shifts compared to the beginning of the shift. Geiger-Brown and colleagues also found night shift nurses to be sleepier toward the end of their shift than day shift nurses. The relationship between long shifts, inadequate sleep, and increased levels of fatigue has been demonstrated in previous research, especially if combined with shift rotations and inadequate recovery time (Trinkoff et al. 2001, Winwood et al. 2006, Stimpfel et al. 2012). Previous studies have also assessed the impact of hours worked on the rate of MEs, showing that the risk of error increased when nurses worked 12.5 hours or more (Rogers et al. (2004), (Scott et al. 2006). However, these studies were limited to questionnaires and self-reported logbooks to evaluate the impact of long working hours on the safety of medication preparation and administration (Rogers et al. 2004, Scott et al. 2006) and ,therefore, a quantitative observational research was conducted (Chapter 4) to evaluate the effect of nurses' fatigue and sleepiness during night shifts on the occurrence of errors and deviations from best practice during IV dose preparation and administration.

5.4. Evaluating the impact of nurses' fatigue and sleepiness on medication safety

Thirty-nine nurses were observed preparing simulated IV tasks at the beginning and the end of the night shift. In addition, background fatigue was assessed at the beginning of the shift, with sleepiness assessed at three points during the shift (start, eight hours and end of shift at 12 hours) using validated scales. Thirteen percent of observations at the beginning of the shift were associated with errors compared to 21% of observations at the end of the shift. However, this difference was not statistically significant. Incorrect dose preparation was the most common type of error observed. All dose preparation errors occurred either during the step of reconstitution of the drug or during the step of withdrawing the drug from the ampoule or vial. These findings are consistent with previous observational studies on IV preparation and administration errors which concurred with common types of errors and error prone steps (Taxis and Barber 2003, McDowell et al. 2010, Westbrook et al. 2011).

Nurses showed low compliance with the steps of hand washing prior to the start of preparation, disinfecting the vial before use, assessing product integrity, mixing the solution after adding the drug, and checking including failure to check the medicine against the prescription at the end of preparation and also failure to obtain a second check when preparing the dose and when setting the infusion pump. These deviations from the best practice were observed during both observation periods and significantly increased at the end of shifts. This might be linked to the impact of the shift length and nurses' sleepiness at the end of the shift. However, other reasons for poor compliance with double checking were discussed in the interviews which included low staffing levels and increased workload.

Perceived levels of fatigue in this thesis (moderate to high levels of acute fatigue and moderate levels of chronic fatigue) were comparable to the levels reported by American and Australian nurses using the same validated scale (Winwood et al. 2006, Barker and Nussbaum 2011). A significant positive correlation between acute and chronic fatigue was identified in the current study. This indicated that increased levels of acute fatigue were usually associated with increased levels of chronic fatigue particularly when associated with short recovery periods between shifts. A transition of acute fatigue to chronic fatigue therefore is expected. It is important to consider the measurements of chronic fatigue levels as well as inter-shift recovery when evaluating the efficiency of extended work shifts for nurses (Barker and Nussbaum 2011).

Increased levels of nurses' fatigue was found to have a significant impact on nurses' health and performance (Winwood et al. 2005). Chronic fatigue was more associated with nurses' malpractice such as taking shortcuts. The comparability of fatigue levels in the current study to that of Barker and Nussbaum (2011) may explain the increased prevalence of deviations from preparation policy observed. Fatigue could be a cause for these deviations from best practice.

The current study showed a significant increase in nurses' sleepiness across night shift. In addition, 39% of nurses reported high level of sleepiness at the end of the shift. The sleepiness recorded by nurses in the current study was higher than the sleepiness recorded among US nurses reported by Geiger-Brown et al. (2012), although both studies reported a significant progression over the study shift. The increased sleepiness

among nurses in the current study was also associated with short sleep duration in 49% of participants. Several studies have demonstrated that insufficient sleep among nurses and other healthcare professionals is a contributor to medical errors. Dorrian et al. (2006) identified that reduced sleep among nurses might be associated with an increased likelihood of making errors and also a decreased likelihood of intercepting errors.

In addition to the significant progression of nurses' sleepiness between the beginning of the shift and the end of the shift, the findings of the current study showed a significant association between being sleepy and making error at the end of the shift i.e. nurses were sleepier at the end of the 12 hour shift and when they were sleepy, they were more likely to make an error. Furthermore, the current study showed a significant decrease in nurses' compliance with best practice at the end of the shift compared with the beginning of the shift. This is consistent with results from the interviews in Chapter 3, that long (12-hour) shifts and night shifts may be important contributors to MAIs particularly when preparing IV doses at the end of night shift when nurses are sleepy and fatigued. This is consistent with studies discussed above which showed a relationship between insufficient sleep and making errors among nurses and other health care professionals. However, these studies relied on questionnaires and self-reported logbooks to report the sleep duration before or between shifts instead of measuring nurses' state of sleepiness during the shift as undertaken in this study. In addition, the current study observed nurses performing a simulated task at the beginning and end of the shift and measured nurses' sleepiness rather than using self-reported errors that nurses identified during the shift. Therefore, the impact of nurses' sleepiness on patient safety at the end of night shift should be considered when assigning tasks such as administration of the morning IV medications.

5.5. Implications for policy and practice

Analysing medication incidents is essential for safe medication use (Cousins et al. 2012). Reporting enables an understanding of the nature of incidents as well as common causes and factors that contribute to incidents. This is important when developing effective risk reduction strategies (Leape 1997, Cousins et al. 2012). Collectively, the studies described in thesis used different methods to provide a detailed analysis of the proportions, types, and causes of MAIs, as well as the impacts of long night shifts on the error rate of IV preparation and administration at one UK NHS Foundation Trust.

An appropriate and regular analysis of incident reports can be used within or across organisations to improve learning from incidents, identify risks, suggest potential solutions, and monitor progress. Furthermore, the investigation of reported incidents supports the sharing of experience nationally and internationally. Therefore, with the increased proportion of MAIs reported, data should be routinely reviewed to identify areas with higher reporting rate of administration incidents. It is also essential that causes and contributing factors for these incidents are identified so prevention strategies can be applied, thereby ensuring the quality and safety of medication use. Promoting the reporting of all MAIs which occur is essential; this may be facilitated by establishing a blame-free reporting culture (Horns and Loper 2002).

Previous incident report analyses have described the overall number of reported incidents; the first study in this thesis compared the number of reported incidents to the total number of OBDs in each clinical area. This approach provides a more reliable view than merely reporting the number of incidents when comparing safety between different areas and identifying areas of higher reporting rate. Therefore, it is important that bed occupancy is taken into consideration when evaluating MAIs. This first study also identified the necessity of applying quality assurance measures to the submitted reports to ensure all necessary information is provided. Some incident reports were submitted without essential information about the incidents, which may affect the quality and usefulness of the reports and limits the benefits of investigating and analysing such incidents (Hua and Gong 2011, Thomas et al. 2011, National Health Service England 2014). It is recommended that key fields in electronic incident report systems be mandatory.

Trust policy states that nurses should not administer medicines before obtaining the required training and completing competency assessments (Trust Drug and Therapeutics Committee 2015). In the second study described in this thesis, nurses highlighted that the training and education provided by the hospital and even universities, including the training provided during the IV dose competency test, was insufficient to assure safe administration of medicines. Interviewees emphasised the necessity of adequate training and suggested extending the training the Trust provides for new nurses. Several studies also recommend providing extended and continuous training to nurses, especially new

staff, to overcome the impact of nurses' lack of knowledge regarding safe medication administration (Prot et al. 2005, Tang et al. 2007, Brady et al. 2009, Ozkan et al. 2011)

Results from the third study described in this thesis demonstrated that deviations from best practice by nurses preparing IV doses were common. In particular, poor compliance with checking steps was common at both observation points. Several causes for such deviations were suggested during interviews with nurses and midwives such as heavy workload and insufficient staffing levels. Causes and contributing factors reported in the interviews can be used to address the poor compliance with the checking steps. In addition, educational programs on IV medication preparation and administration may require review to ensure deviations observed in the current study are included. Finally, the study Trust may wish to consider ongoing competency assessments for IV preparation to reduce deviations from best practice.

The results from the third study described in this thesis also showed a significant association between sleepy nurses and an error occurring at the end of the shift. They were also less likely to comply with the published Trust standards for IV preparation and administration process compared to the beginning of the shift. Nurses and nurse managers should be aware of this finding and take it into consideration when identifying tasks for completion at the end of 12 hour night shifts. Although in the current study fatigue was not related to errors, the moderate to high levels of fatigue and high sleepiness scores of nurses throughout the long shift was a concern. In addition, the insufficient recovery that nurses report obtaining between shifts may exacerbate these issues. Managing the shift length of nurses and also shift allocation is important to allow sufficient rest between shifts as this may reduce fatigue levels and decrease sleepiness during shifts. Nurses' managers should also be aware of levels of both acute and chronic fatigue in their staff and the impact of high fatigue levels on a nurse's health and performance.

Using direct observation, the third study in this thesis collected data regarding nurses' deviations from best practice when preparing IV doses. This has rarely been discussed in previous medication errors research. Collecting such data is important in order to improve the safety of medication administration. This data has identified an area that needs to be discussed and addressed in order to further enhance medication use and

patient safety. Nurses' poor compliance with checking steps can be considered the most important deviation from best practice affecting medication safety.

5.6. Limitations

Several limitations were identified in the methods used in this thesis. In the incident reports study (Chapter 2), potential under-reporting is considered a main limitation of incident reports although voluntary incident reports are considered an accepted method to collect safety data and routinely used (Allan and Barker 1990, Leape and Abookire 2005, Hazell and Shakir 2006, Shojania 2010). The study hospital is the highest reporter of medication incidents across similar NHS Foundation Trusts, with 20% more reports than the next best acute teaching Trust and double the median number of incident reports in acute teaching trusts (National Patient Safety Agency 2013).

A limitation of the incident reports study was the scoring of patient harm, which may vary between individual reporters. However, to minimise this, clear guidance and supporting documents were available on the reporting system and the Hospital Assurance Department also aims to review all incident reports and verify harm. As part of this study the OBD was calculated. The actual number of patients may have been underestimated because the calculation was based on a midnight census, which may have been affected by rapid patient turnover. However, this would only have had a limited effect on MAIs because when medications are due to be administered, there can only be one patient in the bed at that time.

In the interviews study (Chapter 3), generalisability of the results might be limited by the relatively small sample size. However, as no new themes emerged in the final interviews, the sample size was likely to be sufficient for the purpose of this study. In addition, a sampling matrix was used to recruit nurses and midwives of different grades and clinical directorates. Another issue that may limit the generalisability of the results is that the study was only conducted in one hospital and therefore the nurses' views explored may be limited to the study site. However, any effect of this limitation may be reduced as many participants had previous experience in other hospitals and thus provided diverse views. Some interviewees may have been subject to desirability bias (Van de Mortel 2008) and might have presented a favourable and positive image of themselves, their wards or the study trust. However, the research team believe that this

influence was minimal as interviewees were informed about the benefits of such research in improving medication safety, and this helped nurses to feel more comfortable when discussing this sensitive topic. In addition, participants were informed that participations was completely voluntary and confidential.

Finally, some methodological limitations were associated with the observational study (Chapter 4). As simulated tasks were used, nurses were aware that none of the prepared doses were intended for patient administration; therefore, their performance and behaviour might have been affected. The intention was to recruit nurses from different grades (Bands 5 to 7); however, it was only possible to recruit Band 5 and a few Band 6 nurses due to the nature of staff mix on the night shift.

The sample size may be perceived as a limitation of this study, yielding limited observations and a small number of errors, as errors at the end of the shift only increased by 8%, less than the 40% used in the sample size calculation. Nevertheless, the sample size was sufficient to confirm an association between nurses' sleepiness and occurrence of errors. A similar number of participants from medical wards, surgical wards and ICUs were recruited. This study could now be extended to include a wider range of staff grades and cover all clinical areas. Lastly, the two simulated tasks used for this study were not validated for equivalency because of time constraints, although they were developed in collaboration with a specialist pharmacist in injectable medicines safety at the study hospital.

5.7. Further work

In this thesis, incident reports with bed occupancy data were used to evaluate the number of reported incidents to the OBD, types, drugs involved, and severity of MAIs. However, it was not possible to use another denominator, i.e. the number of prescriptions or the number of administered doses, in order to calculate the incident rate of individual drugs. The high number of reported administration incidents associated with some drugs or classes may be linked to their higher rate of prescribing or dose frequency. Identifying incidents associated with specific drugs or groups of medication and "the number of opportunities for incidents with these drugs" may provide more reliable and valid comparison (Kiekkas et al. 2011). With electronic prescribing and medication administration systems being adopted across the NHS, data on drugs

prescribed and doses administered can be captured. Therefore future work could use the number of prescriptions or doses administered as a denominator to provide greater insight into the risk associated with specific drugs or classes.

Dose omissions was the most frequently reported incident in the first study described in this thesis, and many of the drugs reported are considered time sensitive (National Patient Safety Agency 2010, Institute for Safe Medication Practices 2011). Therefore future research could be undertaken in order to further explore reasons for medication administration omission and delay and also to assess the effectiveness of interventions to address this issue. A common problems contributing to omissions and delays identified by interviewees, was poor documentation on drug charts. Documentation weaknesses may be improved by introducing an electronic administration system, which has already been introduced in some clinical areas of the study Trust. Further research is needed to assess whether an electronic administration system improves the rate of documentation errors and reduces omissions and timing errors.

The studies in this thesis indicated that the causes and contributing factors to MAIs are interrelated. Further studies are needed to obtain a better understanding of the nature and role of each factor and how they are related. In particular, further research is needed to investigate factors of interruptions and distractions, staffing level and training, and the relationship between the proportion of registered nurses (experienced nurses) within teams and the rate of MAIs. Future research should also focus on interventions addressing contributing factors that could result in significant and long-lasting improvements in medication safety.

The observational study described in this thesis can be extended to involve all clinical areas, staff grades and include day shifts. This is important to assess whether the impact of nurses' sleepiness on medication errors and deviations from practice is found across clinical areas and during the day shift. Furthermore, given that nurses described increased levels of acute and chronic fatigue with insufficient recovery between shifts in the third study, further research could be undertaken to investigate the relationship between nurses' number of days off between consecutive shifts and their recovery levels. In addition, such research could suggest a minimum rest periods between

consecutive shifts needed by nurses to ensure sufficient recovery and minimise the impact of long work shifts on both nurses' fatigue and patient outcomes.

5.8. Summary of findings

This thesis provided a comprehensive analysis of the reporting rate, types, severity, causes and contributing factors of MAIs in one acute NHS Foundation Trust. The number of MAIs reports to OBDs was calculated and allowed a better comparison between different clinical areas than simply using the number of incidents to determine areas with higher reporting of MAIs. The first study in this thesis identified that more incident were reported during the medication administration stage than during other stages of the MUP. It also identified that omissions or delays, wrong dose, wrong frequency, and wrong infusion rate were the most common reported incidents types.

Nurses' and midwives' views and perceptions of the causes and contributing factors of MAIs in hospital were explored in the second study in this thesis, using semi-structured interviews. Interviews revealed that factors contributing to administration incidents could be related to the work environment, the task of preparing and administering medicines, patients, individual fallibility and institutional deficiencies. Workload, particularly when combined with low staffing levels; frequent interruptions; fatigue and sleepiness associated with long working hours; inadequate nurse training; and lack of communication or miscommunication between nurses or with doctors were mentioned by nurses and midwives as the most common factors contributing to administration incidents.

The impact of nurses' sleepiness during long night shifts on their preparation of IV doses and setting of infusion pumps was investigated in the final study described in this thesis. This was conducted using an observational technique with simulated IV preparation tasks. This study demonstrated that nurses experienced moderate to high levels of fatigue. In addition, high levels of sleepiness were identified among nurses during night shifts with significant sleepiness progression into the end of the shift. No significant relationship was identified between nurses' fatigue and the occurrence of IV medication errors. However, a significant association was found between being sleepy and making errors at the end of the shift. This thesis also revealed that long shifts affected the nurses' compliance with best practice: deviations from best practice while

preparing IV doses at the end of the shift were significantly higher than at the start of the shift.

5.9. Overall conclusion

This thesis highlighted the high proportion of MAIs in hospitals. Analysing incident reports is useful for evaluating and understanding the nature of existing medication-related incidents in hospitals and therefore for developing risk-reduction strategies. Considering the bed occupancy of different clinical areas when determining reported MAI rates may be a better method of identifying areas with higher reporting rate and may therefore help to prioritise risk-reduction strategies and efforts for improvement. In addition, understanding the most common causes and contributing factors of MAIs is essential to improve the safety of medication administration. One of the common factors that may contribute to medication preparation and administration incidents is nurse fatigue and sleepiness during long shifts, especially when they perform medication administration tasks at the end of the shift. A significant relationship was found between being sleepy and making errors among nurses at the end of the shift. Furthermore, long shifts were found to reduce nurses' compliance with best practice when preparing IV medications as deviation from best practice significantly increased at the end of the shift compared to the beginning of the shift. In order to ensure the quality and safety of medication administration, it is essential to address the causes and contributing factors in medication incidents in order to identify potential error reduction strategies for testing and implementation.

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Appendices

Appendix 1. Career questionnaire of interviews study

Career questionnaire

Date: .....

KING'S College LONDON

BDM/12/13-72 An exploratory study to investigate nurses' views of the contributing factors and causes of medication administration incidents in hospital

Medication administration incidents were reported as one of the most frequent types of medication incidents. Many studies in the literature have showed a high incidence of medication incidents during the administration stage over other stages of the medication process. The report of the National Patient Safety Agency (NPSA) on reported medication related incidents in the UK (Safety in Doses, 2009) showed that administration incidents represent the majority of reported incidents accounting 50% of all medication-related incidents. Moreover, studies of medicine administration in hospitals showed a wide variation in the rates of incidents of administration ranging between 3.5 % and 49% (National Patient Safety Agency 2007).

The aim of this exploratory study is to determine the perceptions of nurses of the contributing factors and causes associated with medication administration incidents in hospitals. This will be achieved by conducting face-to-face interviews with nurses involved in medication administration in hospital settings. All nurses involved in drug administration in settings inside hospital in all directorates are eligible to participate. However, to reflect the diversity of nurses' background, a sample of the career questionnaire respondents with different levels of experience and different grade/seniority will be invited for interview. This study has been approved by the Biomedical Sciences, Dentistry, Medicine and Natural & Mathematical Sciences Research Ethics Subcommittee at King's College London (reference number BDM/12/13-72).

If you are interested in participating in this study please read the attached participant information leaflet and complete this **confidential** career questionnaire**.** This questionnaire should take no longer than 5 minutes to complete. Information collected in this career questionnaire will only be used to identify eligible participants for interview. Completing the questionnaire does not necessarily mean that you will be invited for an interview. Should you wish to take part and are selected for interview, the date, time and location will be arranged at your convenience. Please return the completed career questionnaire by (date specified) to the research team using internal mail to: Abdulmajeed Alqasoumi, St. Thomas pharmacy department, or via email to (Abdumajeed.Alqasoumi@gstt.nhs.uk).

If you require more information about this study or have any question about completing this questionnaire, please contact either Abdulmajeed Alqasoumi (Abdumajeed.Alqasoumi@gstt.nhs.uk, Telephone: 020 7848 4853), Dr Cate Whittlesea (Cate.Whittlesea@kcl.ac.uk, Telephone: 020 7848 4796), or Dr Alice Oborne (Alice.Oborne@gstt.nhs.uk, Telephone: 020 718 85019, 5022)

Appendix 1. (Continued) Career questionnaire of interviews study

KING'S College LONDON

Re: An exploratory study to investigate nurses' views of the contributing factors and causes of medication administration incidents in hospital.

This exploratory study aims to determine the perceptions of nurses of the contributing factors and causes associated with medication administration incidents in hospitals. If you are interested to participate in this study please read the attached participant information leaflet and complete this confidential career questionnaire. Information collected in this career questionnaire will only be used to identify eligible participants for interview. Completing the questionnaire does not necessarily mean that you will be chosen and interviewed. Further information about the date, time and location will be provided to nurses invited for interview at a later stage.

Completing and returning this career questionnaire

- ✓ This form should take no longer than 5 minutes to complete.
- ✓ All information provided in this form is confidential.
- ✓ Please return the completed career questionnaire by (date specified) to the research team using internal mail to:
  Abdulmajeed Alqasoumi, care of/ Alice Oborne, St. Thomas pharmacy department,
  or via email to (Abdumajeed.Alqasoumi@gstt.nhs.uk).
- ✓ If you have any questions or require more information about this study, please contact either Abdulmajeed Alqasoumi (Abdumajeed.Alqasoumi@gstt.nhs.uk, Telephone: 020 7848 4853), Dr Cate Whittlesea (cate.whittlesea@kcl.ac.uk, Telephone: 020 7848 4796), or Dr Alice Oborne (Alice.Oborne@gstt.nhs.uk, Telephone: 020 718 85019, 5022)

Appendix 1. (Continued) Career questionnaire of interviews study

Section 1: **Your current job**

1.1. For how long have you been working at Guys' and St. Thomas trust?

☐ Years ☐ Months

1.2. What is your employment status? (Please tick X the appropriate box)

☐ Full time ☐ Part time

1.3. What type(s) of shifts do you work? (Please tick X the appropriate box. You can tick more than one box)

☐ Morning shift ☐ Evening shift

☐ Night shift ☐ Other, please specify.....

1.4. Within this trust, please specify your current title and grade for your main job? (please tick X the appropriate box)

☐ Staff nurse
☐ Midwife
☐ Consultant midwife
☐ Consultant nurse specialist
☐ Practice development nurse
☐ Operating department practitioners
☐ Theatre nurse
☐ Deputy ward manager
☐ Ward manager
☐ Matron
☐ Head of nursing
☐ Associate CN, deputy CN or chief nurse
☐ ***Other,*** please specify.....

Appendix 1. (Continued) Career questionnaire of interviews study

1.5. Which directorate(s) do you work in? (Please tick X the appropriate box)

- ☐ Abdominal Medicine and Surgery
- ☐ Acute Medicine
- ☐ Cardiovascular Services
- ☐ Children's Services
- ☐ Genetics, Rheumatology, Infection, Dermatology, and Allergy (GRIDA)
- ☐ Medical Specialties
- ☐ Oncology and Haematology
- ☐ Perioperative, Critical Care & Pain
- ☐ Surgery
- ☐ Women's Services
- ☐ ***Other,*** please specify.....

Appendix 1. (Continued) Career questionnaire of interviews study

Section 2: **Your previous experience**

2.1. For how long have been registered as nurse? (Please tick X the appropriate box)

☐ Less than two years
☐ 2 – 5 years
☐ 6 – 10 years
☐ 11 – 15 years
☐ More than 15 years

2.2. Are you eligible to administer parenteral (injectable) medicines to patients?

☐ Yes ☐ No (please go to section 3)

2.3. For how long have you been administering parenteral (injectable) medicines to patients?

☐ Years ☐ Months

Section 3: **Your contact details**

Name: (please print) .....

☐ Male ☐ Female

Preferred contact telephone number (optional):.....

Preferred e-mail address:.....

Thank you very much for completing this questionnaire

- Please return the completed career questionnaire by (date specified) to the research team using internal mail to:
  Abdulmajeed Alqasoumi, care of/ Alice Oborne, St. Thomas pharmacy department,
  or via email to (Abdumajeed.Alqasoumi@gstt.nhs.uk).

If you have any questions or require more information about this study, please contact either Abdulmajeed Alqasoumi (Abdumajeed.Alqasoumi@gstt.nhs.uk, Telephone: 020 7848 4853), Dr Cate Whittlesea (cate.whittlesea@kcl.ac.uk, Telephone: 020 7848 4796), or Dr Alice Oborne (Alice.Oborne@gstt.nhs.uk, Telephone: 020 718 85019, 5022)

Appendix 2. Participant information leaflet provided to eligible nurses and midwives for interviews study

Participant Information Leaflet

KING'S College LONDON

YOU WILL BE GIVEN A COPY OF THIS INFORMATION LEAFLET

BDM/12/13-72 An exploratory study to investigate nurses' views of the contributing factors and causes of medication administration incidents in hospital

We would like to invite you to participate in this study, which is a part of PhD research in Clinical Practice and Medication Use at King's College London. You should only participate if you want to; choosing not to take part will not disadvantage you in any way. Before you decide whether you want to take part, it is important for you to understand why the research is being done and what your participation will involve. Please take time to read the following information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information. Thank you for taking the time to read this information sheet.

What is the aim of the research and possible benefits?

Correct administration of medication is a key responsibility of nurses. Factors contributing to medication incidents could have personal, systemic, or managerial causes. Understanding contributing factors and causes of medication administration incidents is essential in order to implement any interventions to reduce the incidents associated with medication administration in hospitals. The aim of this study is to determine the perceptions of nurses of the contributing factors and causes associated with medication administration incidents in hospitals. This study also will identify the nurses' view and opinions about why these causes and factors occur as well as how these contributing factors may be avoided in practice. This aim will be achieved by conducting face-to-face interviews with nurses involved in medication administration in hospital settings. This study has been approved by the Biomedical Sciences, Dentistry, Medicine and Natural & Mathematical Sciences Research Ethics Subcommittee at King's College London (reference number BDM/12/13-72).

Who are we recruiting?

All nurses involved in drug administration in hospital settings from all hospital areas are eligible to participate. However, to reflect the diversity of nurses' background, a sample of nurses with different levels of experience (newly qualified nurses to 10 + years of practice) and different grade/seniority (e.g. ward manager or staff nurse) will be invited for interview. The study will take place in different directorates within the trust and twenty-five nurses from Children's Services, Acute Medicine, Surgery, Perioperative, Critical Care and Pain, Women's Services, Oncology and Haematology, Cardiovascular Services, and Abdominal Medicine and Surgery will be selected and invited to participate.

What will happen if you agree to take part?

If you are interested in participating in this study, you will be asked to complete the attached confidential career questionnaire which should take no longer than 5 minutes to complete. Information collected in this career questionnaire will only be used to identify eligible participants for interview. Should you wish to take part and are selected for interview; you will be invited to participate in a confidential interview with the researcher (Abdulmajeed Alqasoumi). The interviews will carry out in a private area at a suitable venue which you decide is best for you. It will take from 25 to 35 minutes at a convenient date and time. The interview will begin with brief background information about your daily practice in administering medicines. Then we will focus on the area that I am most interested in, which is the causes and contributing factors that may lead to medication administration incidents.

Appendix 2 (Continued) Participant information leaflet provided to eligible nurses and midwives for interviews study

The interview questions will cover the factors related to work environment, the task of preparing and administering medicines, patients you look after, the team you work in, the organisational and management factors, personal factors which relate to individual nurses preparing and administering medicines and factors associated with the preparation and administration of parenteral (injectable) doses. The last section of the interview will focus on your suggestions about barriers that could be implemented to reduce medication incidents occurrence in hospitals.

With your consent, the interviews will be audio-recorded. All data collected for this study are strictly **confidential.**

Are there any possible risks?

During the interview, no sensitive, embarrassing or upsetting topics will be raised or discussed. In addition, you will be able to withdraw from the study at any point up to (date of research report) without giving any reason. Therefore, there is no anticipated reason to believe any participant will suffer any undue distress, harm or injury. Any issue such as potential for disclosure of professional incompetence will be referred to the research supervisor (Dr. Cate Whitlesea) who will then liaise with the relevant hospital manager.

What are the possible benefits?

Your participation will help and inform future developments in the field of medication administration safety in hospitals which will contribute to improving the way patients are managed. Results of this study will be used to develop interventions to help nurses to reduce the frequency of medication administration incidents. If you would like a copy of the results, you will be sent one.

What are the arrangements for ensuring anonymity and confidentiality?

The interviews are confidential and all information disclosed during the course of the research will be anonymised by the researcher and kept strictly confidential. Information used in the research report will NOT be linked back to you. All reports and information collected will be stored securely at Kings College London.

What are the anticipated plans for publication?

The findings of this study will be shared across King's Health Partners. The details of the study will be described in the PhD thesis of the researcher "Abdulmajeed Alqasoumi". The information gained from this study will be widely shared and the results could be published and / or presented at a national or international level.

Participation in this study is **entirely voluntary** and it is up to you to decide whether to take part or not. If you decide to take part you are still free to withdraw from the study **at any point up to** (date of research report) and without giving any reason.

Thank you for reading this information sheet which is yours to keep

Appendix 2. (Continued) Participant information leaflet provided to eligible nurses and midwives for interviews study

Contacts for further information

If you have any questions or require more information about this study, please contact the researcher using the following contact details:

Abdulmajeed Alqasoumi
Tel: 020 7848 4853
Email: Abdulmajeed.Alqasoumi@kcl.ac.uk

If this study has harmed you in any way, you can contact King's College London using the details below for further advice and information:

Dr Cate Whittlesea
King's College London
Franklin-Wilkins Building
150 Stamford Street
London
SE19 NH
Tel: 020 7848 4796
Email: cate.whittlesea@kcl.ac.uk

Appendix 3. Participant's invitation letter for interviews study

Participant invitation letter

BDM RESC Reference:

Dr Cate Whittlesea
Institute of Pharmaceutical Sciences
Room 5.79, 5th Floor
Franklin Wilkins Building
Kings College London
150 Stamford St
London SE1

Date: ……..

BDM/12/13-72 An exploratory study to investigate nurses' views of the contributing factors and causes of medication administration incidents in hospital

We are writing to invite you to participate in a research study that aims to determine the perceptions of nurses of the contributing factors and causes associated with medication administration incidents in hospitals. In this qualitative interview study, participants will be interviewed by a member of the research team for 25 to 35 minutes. This study has been approved by the Biomedical Sciences, Dentistry, Medicine and Natural & Mathematical Sciences Research Ethics Subcommittee at King's College London (reference number BDM/12/13-72).

Background
Medication administration incidents were reported as one of the most frequent types of medication incidents. Many studies in the literature have showed a high incidence of medication incidents during the administration stage over other stages of the medication process. The report of the National Patient Safety Agency (NPSA) on reported medication related incidents in the UK (Safety in Doses, 2009) showed that administration incidents represent the majority of reported incidents accounting 50% of all medication-related incidents. Moreover, studies of medicine administration in hospitals showed a wide variation in the rates of incidents of administration ranging between 3.5 % and 49% (National Patient Safety Agency 2007).

The results of this study will be used to build and extend the current knowledge base to improve patient safety by developing strategies and implementing interventions to reduce such incidents and improve medication administration practice in hospitals.

If you are interested in participating in this study, please read the attached participant information leaflet and complete the enclosed **confidential** career questionnaire. The questionnaire will take approximately 5 minutes to complete. Completing the career questionnaire does not necessarily mean that you will be invited for an interview. Should you wish to take part and be selected for interview, the date, time and location will be arranged for your convenience.

We would like you to reply by (date specified). Please return the completed career questionnaire using internal mail to: Abdulmajeed Alqasoumi, St. Thomas pharmacy department, or via email to (Abdumajeed.Alqasoumi@gstt.nhs.uk).

If you have any questions or require any further information about this study before you make the decision about participating, please contact either Abdulmajeed Alqasoumi (primary contact) by either e-mail (Abdumajeed.Alqasoumi@gstt.nhs.uk) or telephone (020 7848 4853), Dr Cate Whittlesea via (cate.whittlesea@kcl.ac.uk) or (020 7848 4796), or Dr. Alice Oborne via (Alice.Oborne@gstt.nhs.uk) or (020 718 85019, 5022).

Thank you for your time and attention.

Yours faithfully,

Abdulmajeed Alqasoumi	Dr Cate Whittlesea	Dr. Alice Oborne
(Researcher)	(Researcher / PhD supervisor)	(Researcher / PhD supervisor)

Appendix 4. Consent form signed by all interview participants

Consent Form for Participants in Research Studies

Please complete this form after you have read the Information Sheet and/or listened to an explanation about the research.

KING'S College LONDON

BDM/12/13-72 An exploratory study to investigate nurses' views of the contributing factors and causes of medication administration incidents in hospital

King's College Research Ethics Committee Ref:

Thank you for completing and returning the career questionnaire and for considering taking part in this research. The person organising the research must explain the project to you before you agree to take part. If you have any questions arising from the participant information leaflet or explanation already given to you, please ask the researcher before you decide whether to join in. This study has been approved by the Biomedical Sciences, Dentistry, Medicine and Natural & Mathematical Sciences Research Ethics Subcommittee at King's College London (reference number BDM/12/13-72).

You are provided with two copies of this consent form; one is to be returned to the research team, and the other one is for you to keep and refer to at any time. We would be appreciated if the completed and signed consent form is sent by (date specified) using internal mail to: Abdulmajeed Alqasoumi, St. Thomas pharmacy department.

Once we receive your consent form, the researcher, Abdulmajeed Alqasoumi, will contact you to arrange the time and location for your confidential interview which will take place at a time and location convenient for you.

Please tick or initial

- I understand that if I decide at any time during the research that I no longer wish to participate in this project, I can notify the researchers involved and withdraw from it immediately without giving any reason. Furthermore, I understand that I will be able to withdraw my data up to (date of research report). ☐
- I consent to the processing of my personal information for the purposes explained to me. I understand that such information will be handled in accordance with the terms of the UK Data Protection Act 1998. ☐

Participant's Statement:

I _____

agree that the research project named above has been explained to me to my satisfaction and I agree to take part in the study. I have read both the notes written above and the Information Sheet about the project, and understand what the research study involves.

Signature: **Date:**

Investigator's Statement:

I _____Abdulmajeed Alqasoumi_____

Confirm that I have carefully explained the nature, demands and any foreseeable risks (where applicable) of the proposed research to the participant.

Consent Form Page 1

Appendix 5. Interview schedule used for interviewing participants

KING'S College LONDON

Interview Schedule

BDM/12/13-72 An exploratory study to investigate nurses' views of the contributing factors and causes of medication administration incidents in hospital

Introduction *(will be read by the interviewer before the start of the interview)*

Hello, my name is Abdulmajeed Alqasoumi.

Thank you for your willingness to participate in this study which is part of my PhD research at Institute of Pharmaceutical Sciences, King's College London. The study entitled: "an exploratory study to investigate nurses' views of the contributing factors and causes of medication administration incidents in hospital" aims to determine the perceptions of nurses of the contributing factors and causes associated with medication administration incidents in hospitals and I am interested in your thoughts and opinions on these issues. This study has been approved by the Biomedical Sciences, Dentistry, Medicine and Natural & Mathematical Sciences Research Ethics Subcommittee at King's College London (reference number BDM/12/13-72).

During this interview, which will take from 25 to 35 minutes, I will be taking written notes but will also be using an audio tape recorder to help me write a transcript. However, I will delete the audio recording after I have completed the transcription. I may ask you for clarification and examples of the topics discussed. If you have any questions or need any explanation or would like anything clarified, please feel free to stop me at any time.

I would be grateful if you could confirm that you have read the information sheet and that you have read and signed the consent form (*which was already collected by the researcher. Two copies of each form, one will be with the interviewer and the other copy with the participant*).

Before, we start this interview; I would like to check you know that:

- Your participation in this study is completely voluntary
- You are free to refuse to answer any question
- You are free to withdraw from the interview at any time and up to (date of research report)
- The interview will be strictly confidential and anonymised and all information disclosed during this interview will only be available to the research team. Excerpts from this interview may be part of the final report of the research. However, information used in the research report will NOT be linked back to you. All reports and information collected will be stored securely at Institute of Pharmaceutical Sciences.

Interview Schedule Page 1

Appendix 5. (Continued) Interview schedule used for interviewing participants

Background

Firstly, I would like you to give me some background information about your daily practice in administering medicines:

- Now, please can you describe the steps you take when administering an oral medicine from reading the prescription to administering the dose

❖ **A.** Now, we will come to factors related to the work environment

	▪ What factors, if any, in your work environment can increase the risk of administration incidents?	
	▪ From your perspective, why do these happen?	

❖ **B.** Thinking about factors about the task which may affect the quality of care.

	▪ Can you please tell me about what factors, if any, affect the task of preparing and administering medicines and increase the risk of administration incidents?	
	▪ From your perspective, why do these happen?	

❖ **C.** Thirdly, in your clinical area, would you please think about any factors related to the patients you look after which could contribute to an incident?

	▪ Are there any specific group of patients who you believe may be at greater risk of incidents during the preparation or administration of medicines?	
	▪ From your perspective, why do these happen?	

❖ D. Now, thinking about *the team* you work in,

	▪ Can you please tell me what factors, if any, related to how the team works can increase the risk of administration incidents?	
	▪ From your perspective, why do these happen?	

Interview Schedule Page 2

Appendix 5. (Continued) Interview schedule used for interviewing participants

❖ E. Now, we will discuss the organisational and management factors. These are decisions and actions made at higher level in the trust

	▪ What factors, if any, related to the organisation and management can increase the risk of administration incidents?	
	Prompt, o Education and training	
	▪ From your perspective, why do these happen?	

❖ F. Now, can we discuss personal factors which relate to individual nurses preparing and administering medicines.

	▪ From your experience, would you please tell me about such personal factors which could lead to incidents?	
	▪ From your perspective, why do these happen?	

❖ G. From your experience in medication administration, can you please tell me about any other contributory factors which increase the risk of incidents during medicine preparation and administration?

Prompt, if yes

	▪ From your perspective, why do these happen?	

Appendix 5. (Continued) Interview schedule used for interviewing participants

If the participant is involved in preparing and administering parenteral doses

Now, can we discuss factors which specifically increase the risk of incidents during preparation and administration of parenteral (injectable) doses?

- First, could you please describe the steps you take when preparing and administering parenteral (injectable) doses, starting from reading the prescription until the dose has been administered

	▪ Can you please identify any specific factors associated with parenteral (injectable) doses and may lead to incidents?	
	▪ From your perspective, why do these happen?	

Now, we are coming to the last section in this interview which will focus on the barriers to reduce medication incidents occurrence in hospitals

	▪ Could you please tell me what do you feel is the most important issue to resolve?	
	Prompt, ▪ What do you feel are the most important areas that should be looked into to make medication administration safer?	

Finally, I am coming near the end,

Are there any issues you would like to raise?
Is there anything else you would like to add?

Conclusion
Thank you for giving me a lot of information from your experience on medication administration in hospitals. I am really grateful.

I would like to remind you that if you wish to withdraw from the study you will need to inform myself or any other member of the research team before (date of research report)

Interview Schedule Page 4

Appendix 6. Study poster for interviews study

Study poster

KING'S College LONDON

BDM/12/13-72 An exploratory study to investigate nurses' views of the contributing factors and causes of medication administration incidents in hospital

This study has been approved by the Biomedical Sciences, Dentistry, Medicine and Natural & Mathematical Sciences Research Ethics Subcommittee at King's College London (reference number BDM/12/13-72).

Institute of Pharmaceutical Sciences, King's College London

The aim of this study is to determine the perceptions of nurses of the contributing factors and causes associated with medication administration incidents in hospitals.

The aim of this study will be achieved by conducting face-to-face interviews with nurses involved in medication administration in hospital settings. All nurses involved in drug administration in hospital settings from all areas are eligible to participate.

To achieve this aim, you are invited to take part in this study. If you are interested in participating in this study:

- You will be asked to complete a brief career questionnaire
- You may be asked to participate in a face – to – face interview to discuss your views of the contributing factors and causes associated with medication administration incidents in hospitals.

All information collected will be strictly **confidential**. Data from interviews will be **anonymised** during data analysis. It will not be possible to link any information used in the research report back to you.

Your decision to participate in this study is voluntary. There is no obligation to take part in this study and your response will not affect your employment in any way.

If you are willing to take part in this study, please contact the research team by email (Abdumajeed.Alqasoumi@gstt.nhs.uk) to receive a copy of the career questionnaire, participant information leaflet and invitation letter either by email or by internal mail.

For more information about this study before you make the decision about participating, please contact Abdulmajeed Alqasoumi (Abdumajeed.Alqasoumi@gstt.nhs.uk), Dr Cate Whittlesea (cate.whittlesea@kcl.ac.uk), or Dr. Alice Oborne via (Alice.Oborne@gstt.nhs.uk).

Appendix 7. Reminder letter sent to interviews participants

Participant reminder letter

BDM RESC Reference:

Dr Cate Whittlesea
Institute of Pharmaceutical Sciences
Room 5.79, 5th Floor
Franklin Wilkins Building
Kings College London
150 Stamford St
London SE1

Dear.....

Date: .....

BDM/12/13-72 An exploratory study to investigate nurses' views of the contributing factors and causes of medication administration incidents in hospital

Thank you for completing and returning the career questionnaire and for your interest in taking part in this study. We would like to invite you to take part in 25 to 35 minutes interview. As we have not received your consent form we enclose another form with this letter to allow you to confirm your acceptance to take part in this interview. Please read the attached participant information leaflet and ***confirm your acceptance by completing and signing the attached consent form.*** *Please send the completed and signed consent form by (date specified) using internal mail to: Abdulmajeed Alqasoumi, St. Thomas pharmacy department.*

Once we receive your consent form, the researcher, Abdulmajeed Alqasoumi, will contact you to arrange the time and location for your confidential interview which will take place at a time and location convenient for you.

This qualitative interview based study aims to determine the perceptions of nurses of the contributing factors and causes associated with medication administration incidents in hospitals. In this study, participants will be interviewed by the researcher Abdulmajeed Alqasoumi for 25 to 35 minutes. This study has been approved by the Biomedical Sciences, Dentistry, Medicine and Natural & Mathematical Sciences Research Ethics Subcommittee at King's College London (reference number BDM/12/13-72).

Background

Medication administration incidents were reported as one of the most frequent types of medication incidents. Many studies in the literature have showed a high incidence of medication incidents during the administration stage over other stages of the medication process. The report of the National Patient Safety Agency (NPSA) on reported medication related incidents in the UK (Safety in Doses, 2009) showed that administration incidents represent the majority of reported incidents accounting 50% of all medication-related incidents. Moreover, studies of medicine administration in hospitals showed a wide variation in the rates of incidents of administration ranging between 3.5 % and 49% (National Patient Safety Agency 2007).

The results of this study will be used to build and extend the current knowledge base to improve patient safety by developing strategies and implementing interventions to reduce such incidents and improve medication administration practice in hospitals.

If you have any questions or require any further information about this study before you make the decision about participating, please contact either Abdulmajeed Alqasoumi (primary contact) by either e-mail (Abdumajeed.Alqasoumi@gstt.nhs.uk) or telephone (020 7848 4853), Dr Cate Whittlesea via (cate.whittlesea@kcl.ac.uk) or telephone (020 7848 4796), or Dr. Alice Oborne via (Alice.Oborne@gstt.nhs.uk) or telephone (020 718 85019, 5022).

Thank you for your time and your interest in this study.

Yours sincerely

Abdulmajeed Alqasoumi	Dr Cate Whittlesea	Dr. Alice Oborne
(Researcher)	(Researcher / PhD supervisor)	(Researcher / PhD supervisor)

Appendix 8. Study poster for nurses' fatigue and sleepiness study

Guy's and St Thomas' NHS
NHS Foundation Trust

Study poster

KING'S College LONDON

The impact of fatigue on drug preparation and administration

This study aims to assess the impact of fatigue on the safety of medication preparation and administration

All registered nurses involved in preparation and administration of IV medicines and working 12 hour night shifts are invited to take part.

Participation in this study is **voluntary**. There is no obligation to take part and your response will not affect your employment in any way.

All information collected in this study will be strictly **confidential**. It will not be possible to link any information back to you.

If you are interested in participating in this study:

- ✓ Please complete attached selection questionnaire provided which should take no longer than 5 minutes to complete.
- ✓ You may be asked to participate in an observational study using simulated IV preparation and administration tasks.
- ✓ Please also take a participant information leaflet for further information

Please send your completed career questionnaire by internal mail to Abdulmajeed Alqasoumi, c/o Alice Oborne, Pharmacy Department, St Thomas' site, or to Abdumajeed.Alqasoumi@gstt.nhs.uk. Alternatively, you can leave the completed questionnaire in the secure provided box in the ward

For more information before you make a decision about participating, please contact Abdulmajeed Alqasoumi (Abdumajeed.Alqasoumi@gstt.nhs.uk), Dr. Alice Oborne (Alice.Oborne@gstt.nhs.uk), or Dr Cate Whittlesea (cate.whittlesea@durham.ac.uk)

This study has been approved by the Biomedical Sciences, Dentistry, Medicine and Natural & Mathematical Sciences Research Ethics Subcommittee at King's College London (LRS-14/15-1432).

Study poster Page 1

Appendix 9. Participants' selection questionnaire for nurses' fatigue and sleepiness study

Guy's and St Thomas' NHS
NHS Foundation Trust

KING'S College LONDON

Participants' selection questionnaire

Date:

Reference No. (To be filled by the researcher).....

The impact of fatigue on drug preparation and administration

The aim of this observational study is to assess the impact of fatigue on safety of medication preparation and administration. This aim will be achieved by observing a simulated preparation of an injectable medicine at the start and end of a shift. At the same time, fatigue and sleepiness will be measured at the start and end of the shift using validated short questionnaires. During the study shift, you will be given a short diary to record any breaks and/or naps taken during the shift and also to assess your sleepiness score at 8 hours or at the nearest possible time.

This study has been approved by the Biomedical Sciences, Dentistry, Medicine and Natural & Mathematical Sciences Research Ethics Subcommittee at King's College London (LRS-14/15-1432).

If you are interested in participating in this study please read the attached participant information leaflet and complete this confidential questionnaire. Information collected in this questionnaire will only be used to identify and select eligible participants for the study.

Completing and returning this questionnaire

- ✓ This form should take no longer than 5 minutes to complete.
- ✓ All information provided in this form is confidential.
- ✓ **Please return the completed questionnaire by internal post (using the provided envelop) to: Abdulmajeed Alqasoumi c/o Alice Oborne, St Thomas Clinical Pharmacy Offices, or via the ward pharmacist.**
- ✓ **You can leave it in the secure box provided in the ward.**

If you have any questions or require any further information about this study before you make the decision about participating, please contact either Abdulmajeed Alqasoumi (primary contact) by either e-mail (Abdumajeed.Alqasoumi@gstt.nhs.uk) or telephone (020 7848 4853), Dr. Alice Oborne via (Alice.Oborne@gstt.nhs.uk) or telephone (020 718 85019), or Dr Cate Whittlesea via (cate.whittlesea@durham.ac.uk) or telephone (01913340395).

1

Participants' selection questionnaire

Appendix 9. (Continued) Participants' selection questionnaire for nurses' fatigue and sleepiness study

Section I: *Your current job*

1. Within this trust, please specify your current title for your main job? (Please tick X the appropriate box)

- ☐ Staff nurse
- ☐ Consultant nurse specialist
- ☐ Practice development nurse
- ☐ Deputy ward manager
- ☐ Ward manager
- ☐ Matron, Head of nursing, or higher
- ☐ ***Other,*** please specify.....

2. Within this trust, please specify your current grade for your main job? (Please tick X the appropriate box)

☐ Band 5 ☐ Band 6 ☐ Band 7

3. Which directorate(s) do you work in? (Please tick X the appropriate box)

- ☐ Abdominal Medicine and Surgery
- ☐ Acute Medicine
- ☐ Medical Specialties
- ☐ Cardiovascular Services
- ☐ Children's Services
- ☐ Perioperative, Critical Care & Pain
- ☐ Surgery

Other, please specify.....

4. Please specify the ward you work in.....

2

Participants' selection questionnaire

Appendix 9. (Continued) Participants' selection questionnaire for nurses' fatigue and sleepiness study

5. For how long have you been registered as a nurse?

☐ Less than 1 year
☐ 1 to 5 years
☐ 6 to 10 years
☐ 11 to 15 years
☐ 16 to 20 years
☐ 21 to 25 years
☐ More than 25 years

6. For how long have you been administering intravenous medicines to patients (please enter figures in the boxes below)?

Years ☐ Months ☐

7. Which of the following best describes the schedule you USUALLY work at your main nursing job during the last month? (Please select only one by ticking X the appropriate box.)

☐ Regular daytime schedule
☐ Regular evening shift
☐ Regular night shift
☐ 2 shift rotation-days / evenings
☐ 2 shift rotation-days / nights
☐ 3 shift rotation-days /evenings / nights
☐ Irregular schedule arranged by employer
☐ Other, please specify.....

8. Are you usually assigned for any additional responsibilities in your usual shift (rather than direct patient care)?

☐ No ☐ Yes, please specify.....

Section II: *Your contact details*

Name .....

Preferred contact telephone number or e-mail address.....

3

Participants' selection questionnaire

Appendix 9. (Continued) Participants' selection questionnaire for nurses' fatigue and sleepiness study

Thank you very much for completing this questionnaire

- **Please return the completed questionnaire to the research team by:**
  - ✓ Internal mail (using the provided envelop) to:
    Abdulmajeed Alqasoumi, care of/ Alice Oborne, St. Thomas pharmacy department,
  - ✓ Via email to (Abdumajeed.Alqasoumi@gstt.nhs.uk),
  - ✓ Via the ward pharmacist,
  - ✓ You can leave it in the provided box in the nursing tea room

If you have any questions or require more information about this study, please contact either Abdulmajeed Alqasoumi (Abdumajeed.Alqasoumi@gstt.nhs.uk, Telephone: 020 7848 4853), Dr. Alice Oborne via (Alice.Oborne@gstt.nhs.uk) or telephone (020 718 85019), or Dr Cate Whittlesea via (cate.whittlesea@durham.ac.uk) or telephone (01913340395).

4

Participants' selection questionnaire

Appendix 10. Participant information leaflet provided to all eligible nurses about nurses' for fatigue and sleepiness study

Guy's and St Thomas' NHS
NHS Foundation Trust

KING'S College LONDON

Participant Information Leaflet

YOU WILL BE GIVEN A COPY OF THIS INFORMATION LEAFLET

30/09/2015

The impact of fatigue on drug preparation and administration

We would like to invite you to participate in this study, which is a part of PhD research in the Institute of Pharmaceutical Sciences at King's College London. You should only participate if you want to; choosing not to take part will not disadvantage you in any way. Before you decide whether you want to take part, it is important for you to understand why the research is being done and what your participation will involve. Please take time to read the following information carefully and discuss it with others if you want. Ask us if there is anything that is not clear or if you would like more information.

Thank you for taking the time to read this information sheet.

What is the aim of the research and possible benefits?

Correct preparation and administration of medication is a key responsibility of nurses. Intravenous (IV) therapy is a complex process with multiple steps and multiple opportunities for error. The reported error rate during the preparation and administration process of IV doses is higher than other dosage forms. Factors contributing to medication incidents include personal, systemic, or organisational issues. Understanding contributing factors and causes of medication preparation and administration incidents is essential in order to implement any interventions or policies to reduce the incidents associated with medication preparation and administration in hospitals.

It has been shown in previous research that there is a relation between the rate of reported medication preparation and administration errors and increased work shifts hours and fatigue.

In addition, a qualitative research involving 25 interviews with nurses from Guy's and St Thomas' was undertaken to identify nurses' views of causes and contributing factors of medication administration incidents. The nurses identified fatigue associated with long shifts is a major factor especially during night shifts.

The aim of this observational study is to assess the impact of fatigue on the safety of medication preparation and administration. This aim will be achieved by observing a simulated preparation of IV medicine at the start and end of a night nursing shift. At the same time, fatigue and sleepiness will be measured at the start and end of the shift using short validated questionnaires. During the study shift, you will be given a short diary to record any breaks and/or naps taken during the shift and also to assess your sleepiness score at 8 hours or at the nearest possible time.

This study has been approved by the Biomedical Sciences, Dentistry, Medicine and Natural & Mathematical Sciences Research Ethics Subcommittee at King's College London (LRS-14/15-1432).

Who are we recruiting?

All registered nurses involved in preparation and administration of IV medicines and working 12 hour night shifts in the study directorates are eligible to participate. Nurses from acute medicine wards, surgery wards, and critical care units will be involved in this study. The anticipated sample size will be a minimum of 36 nurses who will be recruited to represent areas stated above.

Appendix 10. (Continued) Participant information leaflet provided to all eligible nurses about nurses' for fatigue and sleepiness study

What will happen if you agree to take part?

If you are interested in participating in this study, please complete attached short confidential participants' selection questionnaire which should take no longer than 5 minutes to complete. Information collected in this questionnaire will be used to identify eligible participants for this study. Should you be selected; we will agree a convenient shift for your participation. Your participation will consist of conducting a simulated IV preparation and administration task at start of your night shift and another at the end of the same shift. This will be observed by a researcher and in a subset of cases, for validation, a second researcher will also observe the data collected.

You will also complete a short questionnaire at the beginning and end of the shift to collect some information about your career, the shift and also to assess your fatigue and sleepiness. During the study shift, you will be given a short diary to record any breaks and/or naps taken during the shift and also to assess your sleepiness score at 8 hours or at the nearest possible time.

The preparation tasks will take place on your ward in the usual area for medication preparation (except in critical care it will be prepared in a drug room/area not at the bedside). Your participation will take place outside the shift times (before and after the shift) when you do not have any clinical duties so participation will not interfere with patient care. Observation of IV preparation and completion of the questionnaires is estimated to take between 15-20 minutes. Disturbance to the nurse and ward routine will be kept to a minimum.

What are the tasks' details?

The simulated drug preparations at the start and end of the shift will involve preparing an IV dose and the setup of an IV pump with at least one calculation step. The drugs you will be asked to prepare will be selected from those prepared on the study wards. The simulated drug preparations will not be for patient use, and will be discarded after the observation exercise. The study team are responsible for disposing of the prepared medicine. Independent check will not be available therefore, participants will be asked to tell the observer when they would normally obtain an independent check.

Are there any possible risks?

During your participation in this study, confidentiality will be maintained and it will not be possible to identify you in any publications. All information collected and/or observed will be strictly confidential. Data collected will be used for this research purposes only. In addition, you will be able to withdraw from the study at any point up to one week after the end of the study shift observed without giving any reason. Therefore, there is no anticipated reason to believe any participant will suffer any undue distress, harm or injury. Any issue such as potential for disclosure of professional incompetence will be referred to the research supervisor (Dr. Alice Oborne) who will then liaise with the relevant manager.

What are the arrangements for ensuring anonymity and confidentiality?

Your participation in this study is confidential. All information disclosed or observed during the course of the research will be kept strictly confidential. Information used in the research report will NOT be linked back to you. Feedback on findings will be given as general results, not relating to specific members of staff. All information collected will be stored securely at the pharmacy department in St Thomas hospital or Kings College London. It will not be possible to guarantee that members of your team will not become aware that you are taking part in this study, though any details in relation to your participation will be kept confidential.

What are the possible benefits?

Your participation will help inform future developments in the field of medication administration safety in hospitals which will contribute to improving the way patients are managed. Results of this study will be used to develop interventions and policies to enhance patient safety and to help staff to reduce the frequency of medication preparation and administration incidents. If you would like a copy of the results, you will be sent one.

Participant Information Leaflet Page 2

Appendix 10. (Continued) Participant information leaflet provided to all eligible nurses about nurses' for fatigue and sleepiness study

What are the anticipated plans for publication?

The findings of this study will be shared across King's Health Partners. The details of the study will be described in the PhD thesis of the researcher "Abdulmajeed Alqasoumi". The information and results gained from this study could be published and / or presented at a national or international level.

Participation in this study is **entirely voluntary** and it is up to you to decide whether to take part or not. If you decide to take part you are still free to withdraw from the study at any point up to ***one week*** after the shift observed and without giving any reason.

Thank you for reading this information sheet which is yours to keep

Contacts for further information

If you have any questions or require more information about this study, please contact the researcher using the following contact details:

Abdulmajeed Alqasoumi
Tel: 020 7848 3924
Email: Abdulmajeed.Alqasoumi@kcl.ac.uk

If this study has harmed you in any way, you can contact Dr Alice Oborne using the details below for further advice and information:

Dr. Alice Oborne

Consultant Pharmacist - Safe Medication Practice and Medicines Safety Officer
Pharmacy Department, St Thomas' Hospital, Westminster Bridge Road, London, SE1 7EH

Telephone: 020 718 85019, 5022. Bleep: 1839.

Appendix 11. Consent form signed by all participants in nurses' fatigue and sleepiness study

Consent Form for Participants in Research Studies

Guy's and St Thomas' NHS Foundation Trust

KING'S College LONDON

Reference No. (To be filled by the researcher).....

Please complete this form after you have read the Information Sheet and/or listened to an explanation about the research.

Title of Study: The impact of fatigue on drug preparation and administration

King's College Research Ethics Committee Ref: LRS-14/15-1432

Thank you for considering taking part in this research. The person organising the research must explain the project to you before you agree to take part. If you have any questions arising from the participant information leaflet or explanation already given to you, please ask the researcher before you decide whether to join in. This study has been approved by the Biomedical Sciences, Dentistry, Medicine and Natural & Mathematical Sciences Research Ethics Subcommittee at King's College London (LRS-14/15-1432).

You are provided with two copies of this consent form; one is to be returned to the research team, and the other one is for you to keep and refer to at any time. The researcher will collect this form from you before you start your participation.

Please tick or initial

I confirm that I understand that by ticking/initialling each box I am consenting to this element of the study. I understand that it will be assumed that unticked/initialled boxes mean that I DO NOT consent to that part of the study. I understand that by not giving consent for any one element I may be deemed ineligible for the study. ☐

1. I confirm that I have read and understood the information sheet dated 30/09/2015 for the above study. I have had the opportunity to consider the information and asked questions which have been answered satisfactorily. ☐
2. I understand that my participation is voluntary and that I am free to withdraw without giving any reason at any point within ***one week*** from my participation. ☐
3. I consent to the processing of my personal information for the purposes explained to me. I understand that such information will be handled in accordance with the terms of the UK Data Protection Act 1998. ☐
4. I understand that my information may be subject to review by responsible individuals from the College for monitoring and audit purposes. ☐
5. I understand that confidentiality and anonymity will be maintained and it will not be possible to identify me in any publications ☐
6. I understand that the information I have submitted will be published (anonymously) as a report ☐

Consent Form Page 1

Appendix 11. (Continued) Consent form signed by all participants in nurses' fatigue and sleepiness study

7. In case the information you have submitted is published as a report; I wish to receive a copy of it. ☐

8. I understand that I must not take part if I fall under the exclusion criteria as detailed in the information sheet and explained to me by the researcher. ☐

Participant's Statement:

I _____

agree that the research project named above has been explained to me to my satisfaction and I agree to take part in the study. I have read both the notes written above and the Information Sheet about the project, and understand what the research study involves.

Name of Participant	**Date**	**Signature**

Investigator's Statement:

I Abdulmajeed Alqasoumi confirm that I have carefully explained the nature, demands and any foreseeable risks (where applicable) of the proposed research to the participant.

Signature: **Date:**

If you have any questions or require any further information about this study before you make the decision about participating, please contact either Abdulmajeed Alqasoumi (primary contact) by either e-mail (Abdumajeed.Alqasoumi@gstt.nhs.uk) or telephone (020 7848 4853), Dr. Alice Oborne via (Alice.Oborne@gstt.nhs.uk) or telephone (020 718 85019), or Dr Cate Whittlesea via (cate.whittlesea@durham.ac.uk) or telephone (01913340395).

Thank you for your time and your interest in this study.

Yours faithfully,

Abdulmajeed Alqasoumi (Researcher)	Dr. Alice Oborne (Researcher / PhD supervisor)	Dr Cate Whittlesea (Researcher / PhD supervisor)

Appendix 12. Pre-shift questionnaire used for nurses' fatigue and sleepiness study

Guy's and St Thomas' NHS
NHS Foundation Trust

KING'S College LONDON

Pre-shift Questionnaire

Date:

Reference No. (To be filled by the researcher).....

The impact of fatigue on drug preparation and administration

The aim of this observational study is to assess the impact of fatigue on safety of medication preparation and administration. This aim will be achieved by observing a simulated preparation of an injectable medicine at the start and end of a shift. At the same time, fatigue and sleepiness will be measured at the start and end of the shift using validated short questionnaires. During the study shift, you will be given a short diary to record any breaks and/or naps taken during the shift and also to assess your sleepiness score at 8 hours or at the nearest possible time.

This study has been approved by the Biomedical Sciences, Dentistry, Medicine and Natural & Mathematical Sciences Research Ethics Subcommittee at King's College London (LRS-14/15-1432).

Please complete this confidential questionnaire which involves:

- ✓ Information about your career background
- ✓ Two sections with questions to measure your fatigue and sleepiness levels
- ✓ Some demographic data

This form should not take longer than 5 minutes to complete. All information collected in this questionnaire is confidential and will only be used for the purposes of the study.

This questionnaire will be collected by the researcher when you complete it.

If you have any questions or require any further information about this study or questionnaire, please speak to the researcher.

Appendix 12. (Continued) Pre-shift questionnaire for nurses' fatigue and sleepiness study

Section I: Current nursing job

1. What is the usual length of your shift at your main nursing job?

☐8 hours or less ☐11 to 12 hours

☐9 to10 hours ☐More than 12 hours

2. On average, how many hours per week do you work in your nursing job(s)?(Please tick X the appropriate box)

☐Less than 20 hours ☐61 to 80 hours

☐20 to 40 hours ☐More than 80 hours

☐41 to 60 hours

3. Please complete the table below about your work schedule during the last week

Date	Shift worked (Please tick X the appropriate box)	Length of the shift
……/…../…… (Yesterday)	☐ Off day ☐Day shift ☐ Night shift ☐ Other ……	
……/…../……	☐ Off day ☐Day shift ☐ Night shift ☐ Other ……	
……/…../……	☐ Off day ☐Day shift ☐ Night shift ☐ Other ……	
……/…../……	☐ Off day ☐Day shift ☐ Night shift ☐ Other ……	
……/…../……	☐ Off day ☐Day shift ☐ Night shift ☐ Other ……	
……/…../……	☐ Off day ☐Day shift ☐ Night shift ☐ Other ……	
……/…../……	☐ Off day ☐Day shift ☐ Night shift ☐ Other ……	

4. Do you have any additional paid work other than your main nursing job? (Please tick X the appropriate box)

☐Yes ☐No (go to question 6)

If yes, please list:……

5. On average, how many hours do you work per week in all your jobs?(Please tick X the appropriate box)

☐ Less than 20 hours ☐ 61 to 80 hours

☐ 20 to 40 hours ☐ More than 80 hours

☐ 41 to 60 hours

6. How many hours of sleep did you get, on average, during each 24 hours period over the last week?(Please tick X the appropriate box)

☐Less than 5 hours ☐5 – 6 hours ☐7 - 8 hours

☐9 – 10 hours ☐More than 10 hours

Section II: Fatigue scoring

2Pre-shift Questionnaire

Appendix 12. (Continued) Pre-shift questionnaire for nurses' fatigue and sleepiness study

These Statements are about your experience of FATIGUE and STRAIN at Work and Home OVER THE LAST FEW MONTHS

Circle a number from 0-6: "Strongly Disagree" to "Strongly Agree" which best indicates your response.

	Strongly Disagree	Disagree	Slightly Disagree	Neither Agree or Disagree	Slightly Agree	Agree	Strongly Agree
.) I often feel I'm 'at the end of ny rope' with my work	**0**	**1**	**2**	**3**	**4**	**5**	**6**
:) After a work shift I have little :nergy left	0	1	2	3	4	5	6
;) I never have enough time ›etween shifts to recover my :nergy completely	0	1	2	3	4	5	6
;) I often dread waking up to ınother day of my work	**0**	**1**	**2**	**3**	**4**	**5**	**6**
;) Even if I'm tired from shift, 'm usually refreshed by the tart of the next shift	0	1	2	3	4	5	6
;) My work drains my energy :ompletely every day	0	1	2	3	4	5	6
') Too much is expected of me n my work	**0**	**1**	**2**	**3**	**4**	**5**	**6**
;) I'm often still feeling fatigued rom one shift by the time I tart the next one	0	1	2	3	4	5	6
) I usually have plenty of :nergy left for my hobbies and ›ther activities after I finish vork	0	1	2	3	4	5	6
.0) I rarely recover my strength ully between shifts	0	1	2	3	4	5	6
.1) I often wonder how long I :an keep going at my work	**0**	**1**	**2**	**3**	**4**	**5**	**6**
.2) I usually have lots of energy o give to my family or friends	0	1	2	3	4	5	6
.3) I feel that most of the time 'm just "Living to Work	**0**	**1**	**2**	**3**	**4**	**5**	**6**
.4) Recovering from work atigue between shifts isn't a ›roblem for me	0	1	2	3	4	5	6
.5) I usually feel exhausted vhen I get home from work	0	1	2	3	4	5	6

3Pre-shift Questionnaire

Appendix 12. (Continued) Pre-shift questionnaire for nurses' fatigue and sleepiness study

Section III: Your subjective sleepiness

Please, indicate your sleepiness during the 5 minutes before this rating through circling the appropriate description

1=extremely alert

2=very alert

3=alert

4=rather alert

5=neither alert nor sleepy

6=some signs of sleepiness

7=sleepy, but no effort to keep awake

8=sleepy, some effort to keep awake

9=very sleepy, great effort to keep awake, fighting sleep

Section IV: Demographic information

1. What is your age group? (Please tick X the appropriate box)

☐Under 25 years old ☐45 to less than 55

☐25 to less than 35 ☐55 to less than 65

☐35 to less than 45 ☐More than 65

2. What is your marital status?

☐Single ☐Separated ☐Married

☐Divorced ☐Other (please state) _____

3. Number of dependents (e.g., children, elderly relatives, etc.): (Please tick X the appropriate box)

☐0 ☐1 – 2 ☐3 – 4 ☐More than 4 people

4. What is your highest educational degree?

☐Nursing degree (3 years) ☐ PGDip (2 years)

☐ Master degree ☐ PhD

☐ Other, (please state) _____

Thank you very much for completing this questionnaire

- Please return the completed questionnaire to the researcher

4Pre-shift Questionnaire

Appendix 13. Shift diary used for nurses' fatigue and sleepiness study

Guy's and St Thomas' NHS
NHS Foundation Trust

KING'S College LONDON

Shift diary

Date:

Reference No. (To be filled by the researcher).....

The impact of fatigue on drug preparation and administration

The aim of this observational study is to assess the impact of fatigue on safety of medication preparation and administration. This aim will be achieved by observing a simulated preparation of an injectable medicine at the start and end of a shift. At the same time, fatigue and sleepiness will be measured at the start and end of the shift using validated short questionnaires. During the study shift, you will be given a short diary to record any breaks and/or naps taken during the shift and also to assess your sleepiness score at 8 hours or at the nearest possible time.

This study has been approved by the Biomedical Sciences, Dentistry, Medicine and Natural & Mathematical Sciences Research Ethics Subcommittee at King's College London (LRS-14/15-1432).

Please complete this diary about your shift today which involves:

- ✓ Breaks/naps taken during your shift today
- ✓ Any changes in your patients you are responsible for tonight
- ✓ A question to measure your sleepiness level **which should be filled at 04:00am** if possible or at the nearest available time are involved in patient time

This diary will be collected by the researcher after your shift tonight.

If you have any questions or require any further information about this study or questionnaire, please speak to the researcher Abdulmajeed Alqasoumi or contact him by phone (07546116575)

1Shift diary

Appendix 13. (Continued) Shift diary used for nurses' fatigue and sleepiness study

Section I: Current nursing job

1. What is the usual length of your shift at your main nursing job?

☐8 hours or less ☐11 to 12 hours

☐9 to10 hours ☐More than 12 hours

2. On average, how many hours per week do you work in your nursing job(s)?(Please tick X the appropriate box)

☐Less than 20 hours ☐61 to 80 hours

☐20 to 40 hours ☐More than 80 hours

☐41 to 60 hours

3. Please complete the table below about your work schedule during the last week

Date	Shift worked (Please tick X the appropriate box)	Length of the shift
……/……/…… (Yesterday)	☐ Off day ☐Day shift ☐ Night shift ☐ Other ……	
……/……/……	☐ Off day ☐Day shift ☐ Night shift ☐ Other ……	
……/……/……	☐ Off day ☐Day shift ☐ Night shift ☐ Other ……	
……/……/……	☐ Off day ☐Day shift ☐ Night shift ☐ Other ……	
……/……/……	☐ Off day ☐Day shift ☐ Night shift ☐ Other ……	
……/……/……	☐ Off day ☐Day shift ☐ Night shift ☐ Other ……	
……/……/……	☐ Off day ☐Day shift ☐ Night shift ☐ Other ……	

4. Do you have any additional paid work other than your main nursing job? (Please tick X the appropriate box)

☐Yes ☐No (go to question 6)

If yes, please list:……

5. On average, how many hours do you work per week in all your jobs?(Please tick X the appropriate box)

☐ Less than 20 hours ☐ 61 to 80 hours

☐ 20 to 40 hours ☐ More than 80 hours

☐ 41 to 60 hours

6. How many hours of sleep did you get, on average, during each 24 hours period over the last week?(Please tick X the appropriate box)

☐Less than 5 hours ☐5 – 6 hours ☐7 - 8 hours

☐9 – 10 hours ☐More than 10 hours

Section II: Fatigue scoring

2Pre-shift Questionnaire

Appendix 14. Post-shift questionnaire used for nurse' fatigue and sleepiness study

Guy's and St Thomas' NHS
NHS Foundation Trust

KING'S College LONDON

Post-shift questionnaire

Date:

Reference No. (To be filled by the researcher).....

The impact of fatigue on drug preparation and administration

The aim of this observational study is to assess the impact of fatigue on safety of medication preparation and administration. This aim will be achieved by observing a simulated preparation of an injectable medicine at the start and end of a shift. At the same time, fatigue and sleepiness will be measured at the start and end of the shift using validated short questionnaires. During the study shift, you will be given a short diary to record any breaks and/or naps taken during the shift and also to assess your sleepiness score at 8 hours or at the nearest possible time.

This study has been approved by the Biomedical Sciences, Dentistry, Medicine and Natural & Mathematical Sciences Research Ethics Subcommittee at King's College London (LRS-14/15-1432).

Please complete this confidential questionnaire about your shift tonight which involves:

- ✓ A question to measure your sleepiness level
- ✓ Information about your shift

This form should not take longer than 5 minutes to complete. All information collected in this questionnaire is confidential and will only be used for the study purposes only.

This questionnaire will be collected by the researcher when you complete it.

Post-shift questionnaire

Appendix 14. (Continued) Post-shift questionnaire used for nurse' fatigue and sleepiness study

Section I: Your subjective sleepiness

Please, indicate your sleepiness during the 5 minutes before this rating through circling the appropriate description

1=extremely alert

2=very alert

3=alert

4=rather alert

5=neither alert nor sleepy

6=some signs of sleepiness

7=sleepy, but no effort to keep awake

8=sleepy, some effort to keep awake

9=very sleepy, great effort to keep awake, fighting sleep

Section II: Shift Information

1. Were you assigned for any additional responsibilities in the current shift (rather than direct patient care)?

☐No ☐Yes, please specify.....

2. How many patients you were responsible for in the current shift (please enter figure in the box below)?

☐

3. Using the table below, please report any changes in the patients you were responsible for during your shift today(i.e. newly admitted, died, discharged, or transferred patient(s))

Action occurred	No. of patients
Newly admitted	
Discharged	
Died	
Transferred to the ward	
Transferred from the ward	

Post-shift questionnaire

Appendix 14. (Continued) Post-shift questionnaire used for nurse' fatigue and sleepiness study

4. Have you taken any medication in the last 24 hours?

☐ No ☐ Yes, please list below:

Medication name	Time
.....	.....am / pm
.....	.....am / pm
.....	.....am / pm

Thank you very much for completing this questionnaire

❖ Please return the completed questionnaire to the researcher

Post-shift questionnaire

Appendix 15. Observation instrument for IV preparation and administration

Nurses fatigue and sleepiness study

Observation instrument (page 1)

Drug prepared: .....
Participant's Ref. No: **Ward:**
Observation date: - / /2015 ☐ *Pre-shift task* ☐ *Post-shift task*

Before preparation		
Start time:		
1	Reading and checking the prescription before start	□Yes □No
2	Washing hands before starting preparation	□Yes □No
3	Wearing gloves	□Yes □No
4	Correct diluent	□Yes □No if No Diluent used ……..
5	Correct infusion fluids	□Yes □No if No Infusion fluids……
6	Check expiry date	□Yes □No
7	Check the product integrity and that there is no damage to ampoules or vials	□Yes □No
Preparation process		
8	Correct calculation	□Yes □No
9	Vials disinfected (wiped with alcohol swab)	□Yes □No
10	Correct solvent volume for reconstitution (12 mL water for injection each vial)	□Yes □No □NA ……..mL
11	Check drug completely dissolved (shake for 30 sec)	□Yes □No
12	Correct drug volume withdrawn	□Yes □No……..mL
13	Request volume check before diluting	□Yes □No
14	Remove the needle and attach a filter with a new needle	□Yes □No
15	Add to correct diluent volume ……	□Yes □No
16	Mixing after adding drug	□Yes □No
17	Assessing the appearance of final product? (clear, free from particles, etc)	□Yes □No
18	Checking the medicine against the prescription and ensuring, the correct drug and diluent has been used and it is labelled correctly	□Yes □No
19	Did the nurse keep the vial(s)/ampoules and any unused medicine for checking purposes until	□Yes □No
Administration process		
20	**Setting up the correct infusion rate** Correct volume Correct time	 □Yes □No ..... □Yes □No .....
21	Request independent check	□Yes □No
End time:		

Appendix 15. (Continued) Observation instrument for IV preparation and administration

Observation instrument (page 2)

Labelling the prepared solution			
22	Did the nurse label the contents of syringe or infusion containers	□Yes □No	
23	Did the nurse provide all required information? And correctly?	Drug □Yes □No	Correct? □Yes □No
		Amount □Yes □No	Correct? □Yes □No
		Preparation date and time □Yes □No	Correct? □Yes □No
		Diluent □Yes □No	Correct? □Yes □No
		Total volume □Yes □No	Correct? □Yes □No
		Infusion expiry (date and time) □Yes □No ……	Correct? □Yes □No ……
		Route □Yes □No	Correct? □Yes □No
		Signature □Yes □No	Correct? □Yes □No
		Ward □Yes □No	Correct? □Yes □No

Appendix 16. Image of prescription used in the simulation tasks